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**Increasing walking in individuals with intermittent claudication
The roles of walking treatment and illness cognitions**

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Increasing walking in individuals with intermittent claudication: the roles of walking treatment and illness cognitions

Thesis for Doctor of Philosophy in Health and Social Care Research

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Abstract

Background: Intermittent claudication (IC) is ischaemic leg pain associated with reduced walking ability. Walking is a recommended but underused treatment for IC. The Theory of Planned Behaviour (TPB) and Common Sense Model of Illness Representations (CSM) are frameworks for understanding and changing health behaviours, such as walking, through appropriate behaviour-change techniques (BCTs). This research evaluated cognitions about walking treatment and illness defined by the TPB and CSM, respectively, to inform the development and evaluation of a behaviour-change intervention (BCI) in people with IC.

Methods: Medical Research Council guidelines for developing and evaluating complex interventions informed five studies, including people with IC: a) a systematic review of randomised-controlled trials (RCTs) of interventions applying BCTs targeting walking; b) a qualitative exploration of experiences of and beliefs about walking and IC; c) a cross-sectional observational evaluation of TPB and CSM constructs for explaining walking intention and objective walking ability (6 Minute Walk Distance [6MWD]); d) a feasibility study of an RCT evaluating a physiotherapist-led BCI targeting objective walking behaviour (pedometer step count) and ability (6MWD); and e) a nested qualitative study evaluating the acceptability of the RCT and BCI to participants and a physiotherapist.

Results: a) The systematic review identified 6 RCTs, which reported 11 BCTs. Barrier identification and problem solving, self-monitoring, and feedback on performance were included in effective interventions. b) In the qualitative study (n=19), two themes (and five subthemes) emerged: 1) Walking is an overlooked self-management opportunity (IC is benign and leg pain can be overcome; IC is severe and there is nothing I can do); and 2) Tailored walking guidance is desired (Varied outcome expectations of walking; Barriers to walking to intensity; and Limited purposeful walking for exercise) among people with IC. c) A cross-sectional study (n=142) explained 73% and 28% of variance in walking intention and 6MWD. TPB constructs ($\beta=0.23, 0.35$, and 0.34 for attitude, subjective norm and perceived behavioural control) and perceived consequences ($\beta=0.15$) contributed to walking intention, whereas CSM constructs ($\beta=-0.20, 0.32, 0.22$, and 0.18 for treatment control, personal control, coherence, and risk factor attributions) contributed to 6MWD, beyond past walking behaviour. d) Feasibility of an RCT evaluating a home-based BCI was demonstrated (n=24): intervention adherence (71%), study retention (92%), and treatment fidelity evaluation methods met feasibility criteria, and a moderate treatment effect (Hedges $g=0.39$, 95% CI $-0.47, 1.25$) on objective walking behaviour, but not 6MWD, was found. e) Feasibility and acceptability of the protocol and interventions was confirmed by narrative accounts of participants and the physiotherapist in a nested qualitative study.

Conclusions: The TPB and CSM were evaluated and applied in the systematic development of a walking BCI for people with IC. Few high-quality RCTs were identified which evaluate BCTs targeting walking for IC, walking is overlooked as a self-management opportunity among people with IC who desire tailored walking guidance, and walking treatment cognitions explain walking intention, whereas illness cognitions explain objective walking ability. An RCT evaluating a home-based physiotherapist-led BCI targeting BCTs was feasible, and acceptable to participants with IC and the physiotherapist.

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List of abbreviations

ABPI, ankle–brachial pressure index
BASIC, Baltimore Activity Scale for Intermittent Claudication
BCT, Behaviour Change Technique
BMI, body mass index
BSES, Barrier Self-Efficacy Scale for Intermittent Claudication
CI, confidence interval
CR10, Category–Ratio 10 Scale for Pain
CSM, Common Sense Model of Illness Representations
IC, intermittent claudication
ICC, intraclass correlation coefficient
IPAQ, International Physical Activity Questionnaire
IPQ-R, Revised Illness Perception Questionnaire
MCID, minimal clinically important difference
MD, mean difference
MWA, maximal walking ability
NHS, National Health Service
NICE, National Institute for Health and Care Excellence
NRES, National Research Ethics Service
OR, odds ratio
PAD, peripheral arterial disease
PFWA, pain-free walking ability
RCT, randomised controlled trial
RPE, Rating of Perceived Exertion
SD, standard deviation
SDCQ, San Diego Claudication Questionnaire
SF-12v2, Medical Outcomes Survey Short Form-12 version 2
TASC, Trans–Atlantic Inter-Society Consensus
TPB, Theory of Planned Behaviour
TRA, Theory of Reasoned Action
VEGF, vascular endothelial growth factor
WIQ, Walking Impairment Questionnaire
6MWD, 6 Minute Walk Distance
6MWT, 6 Minute Walk Test

Chapter 1. Intermittent claudication (IC): epidemiology, impact, and treatment

Lower-extremity peripheral arterial disease (PAD) is a long-term atherosclerotic condition, characterised by narrowing or calcification of the arteries supplying oxygenated blood to the legs, and leading to impaired circulation (Haas et al., 2012). This age-related condition (Selvin and Erlinger, 2004) affects up to 20% of the adult population, more than 50% of whom experience associated symptoms of ischaemic exertional leg pain, called intermittent claudication (IC) (Hirsch et al., 2001).

1.1 Pathophysiology of atherosclerotic peripheral arterial disease (PAD)

The initiation of an atherosclerotic lesion involves the recruitment of mononuclear leucocytes (e.g., monocytes and lymphocytes) to the intima of the artery, a process mediated by adhesion molecules (e.g., vascular cell adhesion molecule-1) and inflammatory cytokines (e.g., macrophage chemoattractant protein-1) (Libby, 2000). Mononuclear leucocytes collect in the intima as macrophages, accumulate lipids, and evolve into foam cells, which are indicators of the fatty streak and precursors of atherosclerotic plaque. The atheroma progresses, in particular via the proliferation of smooth muscle cells, which accumulate macromolecules and minerals (e.g., calcium) within their extracellular matrix, contributing to the formation of a fibrous plaque, and clinical atherosclerosis (Hiatt et al., 2001; Ouriel, 2001; Libby, 2000).

Atherosclerotic plaque tends to develop at sites where blood vessels branch, curve, or are irregular, and where sudden changes in velocity and direction of blood flow might occur. Primary conduit vessels frequently affected by PAD include the common iliac, external iliac, common femoral, superficial femoral and popliteal arteries, and disease can be localised or multilevel and diffuse. The location and extent of atherosclerosis has implications regarding the manifestation of symptoms and opportunity for successful revascularisation (e.g., angioplasty or bypass surgery) (Norgren et al., 2007).

In addition to localised effects of atherosclerotic lesions on blood flow, PAD is associated with reduced systemic endothelial function, including flow-mediated dilation and nitric oxide responsiveness, which may contribute to IC and walking impairment (Yang et al., 2008). Chronic inflammation is implicated in the process of endothelial dysfunction, and is associated with IC and with progression of PAD (Silvestro et al., 2002; Belch et al., 2002).

1.2 Classification of PAD and IC

Classifications of PAD help to describe the extent and severity of disease and symptoms. Fontaine et al. (1954) described five stages based on subjective criteria for defining IC (e.g., disability based on self-reported walking distances) (Table 1.1):

- stage I: asymptomatic PAD;
- stage IIa: mild claudication (pain-free walking distance >150 metres);
- stage IIb: moderate to severe claudication (pain-free walking distance ≤150 metres);
- stage III: ischaemic pain at rest; and
- stage IV: PAD with ulceration or gangrene.

Rutherford et al. (1997) expanded the Fontaine classification to include seven categories, subdividing IC into three levels based upon objective treadmill walking distances, including “severe claudication”; in addition, end-stage PAD was broadened to include two levels based on severity and the possibility of salvaging tissue (Table 1.1).

Both classification systems remain widely used, and provide clinical descriptions and criteria for defining PAD severity. However, individual cases which approach category thresholds may be difficult to define, and the classifications might be more applicable in research than in clinical settings, where more detailed haemodynamic assessment would be required to confirm a diagnosis and therapeutic decision (Rutherford et al., 1997).

Table 1.1 Classification of peripheral arterial disease (PAD) defined by Fontaine grade or Rutherford category

Fontaine grade	Rutherford category	Clinical description	Objective criteria ^a
I	0	Asymptomatic (no haemodynamically significant occlusive disease)	Normal treadmill or reactive hyperaemia test
IIa	1	Mild claudication	Completes treadmill exercise ^b ; post-exercise AP>50 mmHg but at least 20 mmHg lower than resting value
IIb	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise ^b and post-exercise AP<50 mmHg
III ^c	4	Ischaemic rest pain	Resting AP<40 mmHg, flat or barely pulsatile ankle or metatarsal PVR; TP<30 mmHg
IV ^c	5	Minor tissue loss: non-healing ulcer, focal gangrene with diffuse pedal ischaemia	Resting AP<60 mmHg, ankle or metatarsal PVR flat or barely pulsatile; TP<40 mmHg
	6	Major tissue loss: extending above TM level, functional foot no longer salvageable	Same as category 5

Reproduced from Norgren et al. (2007) with permission from Elsevier. ^aRutherford classification. ^bFive minutes at 3.2 kilometres/hour on a 12% incline. ^cGrades III and IV (Rutherford categories 4–6) describe critical limb ischaemia. AP, ankle pressure; PVR, pulse volume recording; TM, trans-metatarsal; TP, toe pressure.

1.2.1 Classic and atypical IC

The Fontaine and Rutherford classifications describe symptoms in terms of objective or haemodynamic severity; however, IC can be defined further by its location and manifestation. Two broad categories exist: classic IC and atypical exertional leg pain (i.e., atypical IC). Classic IC, is described as exertional pain, located in the calf, that requires the individual to stop walking and resolves within 10 minutes of rest, but does not begin at rest or resolve during walking (Rose and Blackburn, 1968; Rose, 1962), and affects approximately 30% of people with

PAD (Wang et al., 2005). Up to 50% of individuals with PAD experience atypical IC, which includes pain in muscle groups other than the calves (i.e., the buttock or thighs), or pain that individuals are able to continue walking through (Hirsch et al., 2001; McDermott et al., 2001). In both classic and atypical IC, the imbalance of blood flow and metabolic demands generate ischaemic pain or discomfort in the lower extremities that affects walking.

Many research studies, including the studies in this thesis do not differentiate between classic and atypical symptoms, and utilise the generic term “IC”.

1.3 Detection and diagnosis of PAD and IC

PAD can be detected and diagnosed by non-invasive markers. Palpation of arm, leg, and pedal pulses is used to identify and locate abnormalities. Alongside palpation, the presence of IC can aid detection. However, pedal pulses are variable and can overestimate the presence of disease, whereas reliance on the presentation of symptoms alone leads to under-diagnosis, so reliability of these methods is limited (Norgren et al., 2007; Criqui et al., 1985).

A sensitive, non-invasive test is the ankle–brachial pressure index (ABPI), which provides a simple haemodynamic measure of blood flow capacity. The ABPI is calculated as the ratio of maximum blood pressure measured at the dorsalis pedis and/or posterior tibial arteries compared with the maximum blood pressure at the left or right brachial artery. Large-vessel PAD is defined as a resting $ABPI \leq 0.90$ in either leg (Norgren et al., 2007) (Table 1.2).

Table 1.2 Interpretation of the ankle–brachial pressure index for defining PAD

Resting ankle–brachial pressure index	Definition
≥ 1.30	Non-compressible vessel
1.00–1.29	Normal blood flow
0.91–0.99	Borderline peripheral arterial disease
0.41–0.90	Mild to moderate peripheral arterial disease
≤ 0.40	Severe peripheral arterial disease

Specificity of a resting ABPI ≤ 0.90 for detecting moderate PAD (e.g., $\geq 50\%$ stenosis) is 83–99%, although sensitivity is lower (15–79%) (Dachun Xu et al., 2010), and so the ABPI might not be sufficient for detecting PAD that is mild or located in calcified vessels (Stein et al., 2006). Additional tests are recommended for symptomatic and at-risk individuals in clinical settings, and include pulse volume recordings (arterial waveforms detected by plethysmograph, which detects and graphically records changes in pulse contour and amplitude), post-exercise ABPI measurements or post-occlusive reactive hyperaemia (a decrease from resting or baseline ABPI indicates PAD), and resting blood flow velocity (detected by continuous wave Doppler, with triphasic waveforms indicating normal blood flow, and biphasic and monophasic waveforms indicating PAD) (Stein et al., 2006). For individuals with PAD being considered for revascularisation, angiography, duplex ultrasound, magnetic resonance imagery, or computed tomographic angiography are methods used to assess the degree and suitability of atherosclerotic lesions for intervention. Duplex ultrasonography enables the quantification of stenoses based on waveform analysis and peak systolic velocity (Table 1.3) (Norgren et al., 2007; Begelman and Jaff, 2006).

Table 1.3 PAD severity based on stenosis grade obtained by duplex ultrasound

Pattern of peak systolic velocity	Stenosis grade	Interpretation
Normal waveform, no change in peak systolic velocity	0%	Normal (no stenosis)
Change in waveform, no change in peak systolic velocity	1–19%	Mild stenosis
Increase in peak systolic velocity of 30–100% relative to proximal normal segment	20–49%	Moderate stenosis
Increase in peak systolic velocity of $>100\%$ relative to proximal normal segment	50–99%	Severe stenosis
No flow identified in the artery	100%	Occlusion

A low ABPI diagnoses PAD, and is associated with greater walking impairment, but not with the type of symptom manifestation (McDermott et al., 2010). Given the subjective nature of pain presentation, IC is diagnosed primarily by self-report and combined with objective criteria (described above) to determine health status and treatment approach. Clinically, individuals are asked to describe their symptoms and the extent of functional limitations in their own words. Validated questionnaires that systematically screen for symptoms (Schorr and Treat-Jacobson, 2013), and standardised treadmill- or corridor-based protocols that induce or quantify symptoms, are more commonly used in the research setting (Section 1.6.1; Chapter 3). The San Diego Claudication Questionnaire (SDCQ; Chapter 3) is a validated survey for identifying and categorising PAD symptoms, and is sensitive (69.9–96.1%) and specific (46.5–81.8%) for detecting PAD compared with the ABPI, history of revascularisation, or post-tibial and tibial-peroneal blood pressures (Schorr and Treat-Jacobson, 2013). In many instances, confirmation of IC requires differential diagnosis, particularly to exclude neuropathic pain related to diabetes or spinal degeneration (Schorr and Treat-Jacobson, 2013).

1.4 Prevalence of PAD and IC

Due to discrepancies in criteria and methods for detecting PAD (Reed et al., 2009), alongside differences in population characteristics, the total prevalence of PAD is not well established (Mohler and Giri, 2008), and rates vary between approximately 1.5–20% (Cimminiello et al., 2011; Diehm et al., 2004). Among individuals with PAD, approximately 50% experience IC (Hirsch et al., 2001). The location of atherosclerosis might affect the manifestation of leg pain, with the highest prevalence of IC occurring when disease is present in multiple vessels in either one leg or both (Hiatt et al., 1995).

The Prevalence of Peripheral Arterial Disease in Patients with a Non-High Cardiovascular Disease Risk, with no Overt Vascular Diseases nor Diabetes Mellitus (PANDORA) study enrolled 9,816 adults with at least one cardiovascular disease risk factor from primary care practices across six European countries, and detected asymptomatic PAD among 17.8% of the sample

(Cimminiello et al., 2011), suggesting that PAD may be largely underdiagnosed. However, 97.4% of participants were White, and ethnicity is an important risk factor for PAD not captured by that study.

1.5 PAD and IC risk factors and comorbid conditions

PAD is linked to modifiable risk factors common with systemic atherosclerosis, including dyslipidaemia, diabetes, hypertension, and tobacco smoking (Murabito et al., 1997). PAD is associated with a two- to threefold increased risk of cardio- and cerebrovascular morbidity and mortality (Leng et al., 1996; Diehm et al., 2004; Criqui et al., 1997), and risk factor management is a focus of PAD treatment (Norgren et al., 2007). Compared with asymptomatic PAD, the risk of cardiovascular morbidity and mortality is heightened among those who experience IC (Criqui et al., 1997).

Physical inactivity increases cardiovascular risk among individuals with IC. People with IC are less active compared with healthy individuals, and less than one-half achieve public health physical activity guidelines for general cardiovascular health (Department of Health, 2011), or for improving IC (Lauret et al., 2014; McDermott et al., 2002). Lower daily physical activity is associated with a higher rate of decline in IC symptoms (Garg et al., 2009), and up to 2.1-fold and 3.5-fold increased risk of a cardiovascular event or all-cause mortality, respectively (Garg et al., 2006).

Age and ethnicity are additional, non-modifiable risk factors for PAD. The prevalence of PAD increases from approximately 3–4% in adults aged ≥ 40 years (Murabito et al., 2002) to 15–20% in individuals aged >70 years (Selvin and Erlinger, 2004; Criqui et al., 1997). The age-dependent prevalence of PAD among women may be lower than for men, although the total prevalence of PAD, and that of borderline PAD (i.e., ABPI 0.90–1.00), is equal or higher among women (Hirsch et al., 2012; Hiramoto et al., 2014); however, it is unclear whether there are gender differences in the onset, progression and outcome of PAD (Walker and Hiramoto, 2012). Black ethnicity (i.e., African or Caribbean descent) is associated with atherosclerotic risk factors,

including increased hypertension, diabetes, and body mass index (BMI) (Meadows et al., 2009; NHS Health and Social Care Information Centre, 2005), and a higher prevalence of PAD. Among an observational sample of 2343 participants in The San Diego Population Study, 4.4% had PAD, with a 2.3-fold increased risk among Black individuals, which was only partly attributable to cardiovascular risk factors (Criqui et al., 2005). The Multi-Ethnic Study of Atherosclerosis, including 6653 individuals in the United States, reported an odds ratio (OR) of 1.47 (95% confidence interval [CI] 1.07, 2.02) for Black ethnicity, after controlling for atherosclerotic risk factors, and interleukin-6, fibrinogen, and D-dimer, which suggests potential mechanisms underpinning ethnic differences (Allison et al., 2006).

1.6 The impact of PAD and IC

The direct impact of IC on individuals with PAD includes impaired walking ability, physical function and health-related quality of life (Treat-Jacobson et al., 2002; McDermott et al., 2001), and places a significant cost on the National Health Service (NHS) and burden to individuals and society (Michaels et al., 2000).

1.6.1 The impact of PAD and IC on walking ability and physical function

Frequently used objective assessments used to quantify the impact of IC on walking ability include standardised treadmill- and corridor-based walking tests. Treadmill protocols (e.g., initial 3.2 kilometres/hour and 0% grade, increasing grade by 2% every 2 minutes) (Gardner et al., 1991) are used to elicit two self-reported disease-specific parameters: 1) the pain-free walking ability (PFWA), which reflects the distance or time walked before the perceived onset of IC; and 2) the maximal walking ability (MWA), which is the distance or time walked before IC causes the individual to stop and rest. The 6 Minute Walk Test (6MWT) is a corridor-based assessment that provides a valid and reliable measure of walking ability, reported as the 6 Minute Walk Distance (6MWD; Chapter 3), and can be used to obtain the PFWA and MWA, although some individuals with IC may not achieve these parameters at a constant, self-selected pace.

Individuals with PAD walk shorter distances (up to 136 metres less in a 6MWT) and more slowly (by 0.13 metres/second over 4 metres, or 12% slower at usual pace) compared with healthy controls (McDermott et al., 1998). 6MWD declined by up to 80 feet (25 metres) over 12 months in a sample of 417 individuals with PAD (McDermott et al., 2006). Adjusting for age and gender, individuals with PAD had a higher rate of self-reported mobility loss (defined as inability to walk 400 metres or up and down one flight of stairs; hazard ratio 1.63, 95% CI 1.03, 2.56) and an increased risk (hazard ratio 2.17, 95% CI 1.42, 3.32) of achieving their MWA during a 6MWT compared to individuals without PAD over a median 50 month follow-up period (McDermott et al., 2007). These data include people with IC and asymptomatic PAD, and as a result it is difficult to discern the degree to which walking impairment is associated with IC alone.

There is an inconsistent association between PAD symptomology and walking ability among people with or without IC. There were no differences in objective ambulatory measures (400 metre walk time and 4 metre walk speed) between people with IC (n=77) or asymptomatic PAD (n=143), controlling for age, sex, smoking, BMI, self-reported physical activity, and common comorbidities. However, only older adults (aged 70–89 years) were included, and so findings might not reflect younger people with PAD (McDermott et al., 2013a). Associations are also inconsistent for perceived walking ability, reported on the self-administered Walking Impairment Questionnaire (WIQ), a 14-item validated disease-specific measure, including walking shorter distances, slower speeds, and having greater difficulty climbing stairs (McDermott et al., 1998). Individuals with IC reported shorter walking distances than individuals with asymptomatic PAD on the WIQ, but similar walking speeds and stair climbing abilities (Collins et al., 2005). However, only 67 participants were included, comparisons did not control for key sociodemographic variables (e.g., age, sex, ethnicity) or comorbidities, and the WIQ may be less accurate for moderate walking impairment compared with extreme scores (i.e., <18 or >67 out of 100) (McDermott et al., 1998).

Among individuals with symptomatic PAD, the impact of symptom type is also equivocal. One study found individuals with classic IC (n=150) walked shorter distances (328.5 versus 391.6 metres) and were more likely to stop (16% versus 6.8%) during a 6MWT compared with individuals reporting atypical IC (n=131) (McDermott et al., 2001). However, there were no significant differences in 4 metre walk speed, tandem stand, or chair raises. While 150 participants with classic IC were included, subgroups of atypical IC were explored (e.g., individuals who reported carrying-on versus stopping walking due to IC), so that study may have been underpowered to detect differences between groups across multiple comparisons. Among 715 participants with IC, there were no differences in distances walked during treadmill and corridor walking tests, self-reported walking ability (measured by the WIQ), self-reported and accelerometer-based physical activity, and health-related quality of life between individuals who reported classic or atypical IC (Gardner et al., 2007). However, that study included mostly men (80%), and participants who reported atypical IC presented symptoms consistent with classic IC on a graded treadmill test, suggesting participants were inaccurately classified on study enrolment.

While the evidence reviewed indicates that PAD reduces walking ability compared with healthy individuals, the impact of symptom presence and type (i.e., classic versus atypical IC) is unclear.

1.6.2 The impact of PAD and IC on health-related quality of life

Compared with age- and sex-adjusted norms, people with PAD report lower overall health-related quality of life (Pell, 1995; Regensteiner et al., 2008). The impact of PAD on quality of life is comparable to that of other cardiovascular diseases (e.g., coronary artery disease), in particular with regard to aspects of physical functioning; however, PAD has an additive effect on impairment, with individuals who have combined cardiovascular disease and PAD reporting the lowest functioning (Regensteiner et al., 2008).

Measures of walking ability (e.g., derived from treadmill or corridor tests) tend to better reflect the impact of symptomatic PAD on quality of life, compared with clinical parameters reflecting disease severity (e.g., ABPI) (Izquierdo-Porrera et al., 2005; Spronk et al., 2007). For example, in 80 people with IC, ABPI was associated with pain-related and physical functioning ($r=0.30$ and 0.42 , respectively), whereas 6MWD was associated with broader aspects of quality of life including physical, mental, and general health, and vitality ($r=0.28-0.42$) (Izquierdo-Porrera et al., 2005) measured by the Medical Outcomes Survey Short Form-12 (SF-12), a brief, standardised, and valid measure of mental and physical functioning over the past 7 days (Ware et al., 1996). However, that study included mostly male participants (87%) and may not reflect women with IC, and reported only Pearson correlation coefficients, therefore results do not indicate agreement or explore multivariate effects.

Two qualitative investigations aid in further understanding the impact of IC. Treat-Jacobson et al. (2002) interviewed 38 individuals with PAD ($n=25$ men, mean age 65 years) to explore the effect of their diagnosis and treatment on health-related quality of life. Pain and walking impairment were central to the experience of PAD, and participants described limitations and avoidance of physical activities, altered social and recreational activities, feelings of uncertainty or fear, and compromised self-identity including feeling aged, abnormal, or ashamed by symptoms. Participants included individuals with IC, and with a range of disease severities, including critical limb ischaemia (e.g., Fontaine stage III-IV) in the United States. However participant ethnicity and previous treatment were not reported, so whether the sample represented these characteristics of the IC population is unclear, and findings may not be generalisable to individuals in the United Kingdom (UK). A qualitative investigation conducted in Sweden, and including 15 individuals with IC ($n=7$ women, mean age 73 years), reported a need for individuals to adjust to a restricted life, which was illustrated by perceptions of burdening others when having to stop during a walk, longing for one's previous lifestyle, the need to incorporate IC into daily life, and leading a strenuous life with IC (Egberg et al., 2012). Participants described frustration, fury, and exasperation as a result of their IC. The sample included only older adults (range 64–81 years), and so does not represent the

range of individuals with IC, and while authors reported sampling purposively for duration of symptoms, data are not reported on this clinical characteristic so it is unclear whether a representative sample was achieved.

Given the profound impact of PAD, and particularly IC, on walking ability, physical function, and quality of life, efficient management, which targets symptoms, is a healthcare priority (NICE, 2012).

1.7 Management of IC

1.7.1 Treatment aims for individuals with IC

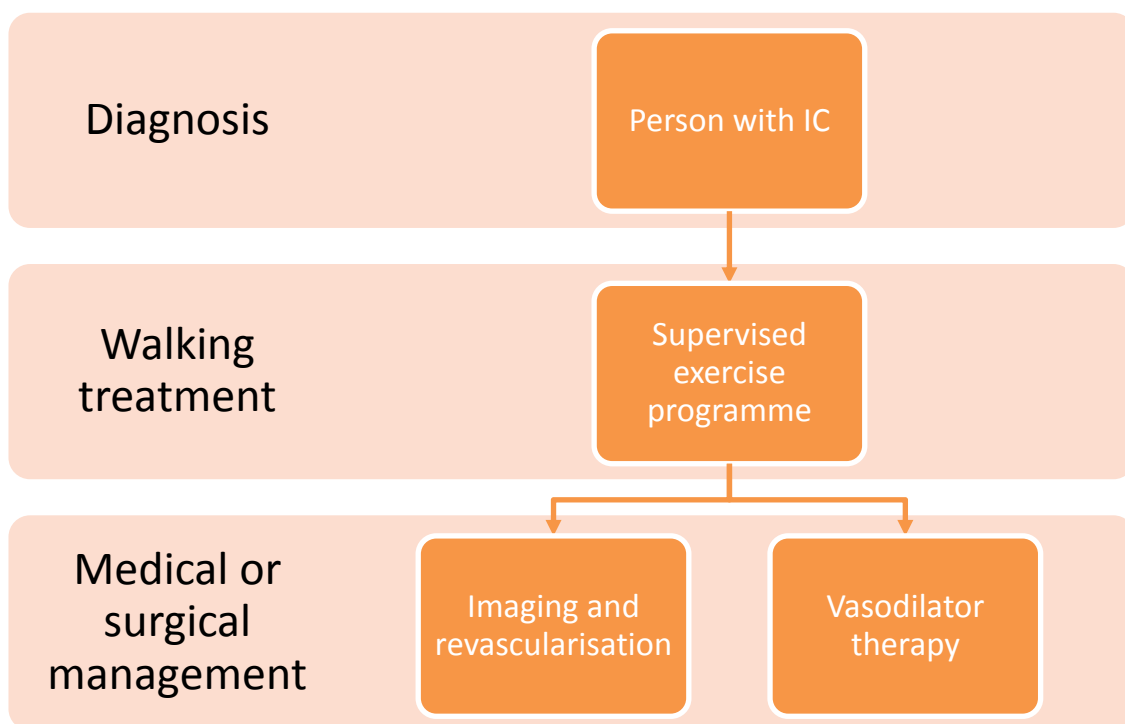
Management of IC addresses systemic atherosclerosis as well as lower-limb disease and symptoms (Norgren et al., 2007). Specifically, treatment targets include the following:

- a) IC, aiming to alleviate leg pain in order to improve walking performance and daily functional ability;
- b) PAD, aiming to improve blood flow to the lower extremities, preventing tissue damage and limb loss; and
- c) systemic disease, aiming to modify risk factors for cardiovascular disease and halt the progression of atherosclerosis.

1.7.2 The pathway of care for individuals with IC

Management of IC includes supervised exercise therapy, primarily consisting of walking, as the initial approach (Norgren et al., 2007; NICE, 2012) (Figure 1.1), which aims to improve walking ability (e.g., MWA, PFWA). Naftidrofuryl oxalate, a vasodilator licensed in the UK for treating IC, is recommended only after supervised exercise therapy is trialed (NICE, 2012). If these strategies are unsuccessful, revascularisation (i.e., angioplasty or bypass surgery) may be considered; in selected individuals with a proximal occlusion and progressing, debilitating symptoms, invasive procedures may be considered as a first-line treatment in order to address IC and restore blood flow to the limb (Norgren et al., 2007). However, elective invasive procedures demonstrate only short-term improvements in walking ability compared with conservative management (Murphy et al., 2011), and carry greater risk for the individual with IC.

Figure 1.1 Pathway for management of intermittent claudication (IC) recommended by the UK National Institute for Health and Care Excellence



National Institute for Health and Care Excellence (2015). Adapted from “Managing intermittent claudication in people with peripheral arterial disease”. Reproduced with permission.

Risk-factor modification is recommended for all individuals with PAD, to prevent a cardiovascular event and progression of lower-limb atherosclerosis. Recommendations include referral to smoking cessation services, weight reduction among individuals with a BMI ≥ 25 kg/m², lipid control through dietary changes or statin therapy, aggressive glycaemic control with a glycated haemoglobin goal of <7%, blood pressure control to <140/90 mmHg or, for people with diabetes or renal insufficiency to <130/80 mmHg, and antiplatelet therapy (SIGN, 2006; Norgren et al., 2007). The overall effect of cardiovascular risk reduction on IC has not been described; however, the use of statins for cholesterol management is associated with improved IC and walking ability. Hypothesised mechanisms for the effect of statins on IC include changes in endothelial function, plaque stabilisation, and attenuation of the inflammatory response (Coppola and Novo, 2007).

1.7.3 Guidelines for walking treatment for IC

Supervised exercise therapy is currently endorsed as initial treatment for individuals with IC by the American College of Cardiology Foundation/American Heart Association (ACC/AHA) and the Trans-Atlantic Inter-Society Consensus (TASC)-II Group (Norgren et al., 2007; Hirsch et al., 2006). The ACC/AHA recommends a minimum of 30–45 minutes of supervised walking exercise ≥ 3 times per week for ≥ 12 weeks (Hirsch et al., 2006). Similarly, TASC-II guidelines advise supervised track or treadmill walking for 30–60 minutes per session conducted 3 times per week for 3 months (Norgren et al., 2007). To maximise the training response (e.g., increased walking ability), walking should be performed at a speed or grade that induces claudication within 3–5 minutes, and the individual should walk beyond the onset of pain to the point when claudication is perceived as moderate in intensity (Norgren et al., 2007).

Consistent with these guidelines, the National Institute for Health and Care Excellence (NICE) identifies the provision of supervised exercise therapy as a priority for implementation within the NHS. Specifically, it recommends 1) offering 2 hours per week of supervised exercise therapy for a 3 month period and 2) encouraging people to exercise to the point of maximal pain (NICE, 2012). Quality Standards issued in 2014 by NICE suggest poor guideline implementation nationally, and identify variation in the provision of supervised exercise therapy across the UK and a need both for new provision and improvement in existing care (NICE, 2014a). A key quality statement recommends that all individuals with IC are offered supervised exercise therapy, and suggests that greater use of conservative strategies, including advice on risk factor modification and exercise, could reduce the need for more invasive treatment and improve outcomes.

The focus of this thesis will be on individuals with Fontaine stages IIa and IIb (Rutherford categories 1–3), as evidence underpinning walking treatment guidelines for PAD includes individuals falling within these categories (i.e., IC).

1.7.4 Effectiveness of walking treatment for IC

Walking ability in people with IC consistently improves with supervised exercise therapy. In a meta-analysis of 21 exercise interventions, Gardner and Poehlman (1995) reported an increase of 179% and 122% in PFWA and MWA in people with IC, respectively. A Cochrane review including 30 randomised controlled trials (RCTs) found similar results, with a mean difference (MD) favouring supervised exercise therapy over usual care of 108.99 metres (95% CI 38.2, 179.8) and 82.29 metres (95% CI 71.86, 92.7) in PFWA and MWA, respectively (Lane et al., 2014). In both reviews, however, the components and dosage of exercise interventions varied, and incorporated strength training or cycle ergometry, making it difficult to isolate the effect of walking exercise on outcome. However, walking exercise was identified as a feature of interventions associated with the greatest improvements, alongside a duration of ≥ 6 months, and exercise intensity reaching near-maximal pain (Gardner and Poehlman, 1995). In addition, while cycle ergometry, arm ergometry, and lower-extremity aerobic exercises demonstrate at least moderate effects on walking ability, treadmill walking exercise produces comparatively greater effects on PFWA and MWA according to findings of a systematic review including 36 studies (n=1644 participants) (Parmenter et al., 2011). However, study quality was modest due to limited blinding of assessors, allocation concealment, or intention-to-treat analyses, and few trials (11%) evaluated modes of therapy other than lower-limb aerobic exercise (e.g., walking). In addition, women and older adults with IC were under-represented by included studies.

Supervised exercise therapy may be more effective in improving MWA and PFWA when compared to standard pharmaceutical therapy (Murphy et al., 2011; Gardner et al., 2011) and revascularisation (Murphy et al., 2011; Watson et al., 2008). Gains in walking ability are associated with increases in daily physical activity and improvements in overall ambulatory function, including stair climbing (Gardner et al., 2001; Gardner et al., 2000). Improvements in health-related quality of life following supervised exercise therapy are inconsistent and limited by the range of outcome measures used, including generic (e.g., SF-36) and disease-specific

surveys (e.g., Vascular Quality of Life Questionnaire), and because health-related quality of life is often reported as a secondary outcome, so studies are not powered to detect a change (Gardner et al., 2005; Tsai et al., 2002; Watson et al., 2008).

1.7.5 Mechanisms for benefits of walking treatment for IC

Key hypothesised mechanisms for the effects of walking on IC include microvascular changes affecting the skeletal muscle (i.e., angiogenesis), macrovascular changes to the arterial tree (i.e., arteriogenesis). Additional factors that may support walking improvements include reduced systemic inflammation, central adaptations, changes to blood rheology, and gait alterations.

Angiogenesis. Exercise, including walking, increases capillary density and mitochondrial enzyme activity in people with IC, allowing greater oxygen extraction by the muscle (Lundgren et al., 1989). Metabolic, hypoxic and/or mechanical factors are implicated in the stimulation of angiogenic processes (Figure 1.2).

Metabolic processes include the production of extracellular adenosine by adenosine triphosphate released during exercise. Compared with healthy populations, people with PAD experience a prolonged initial anaerobic phase with the onset of exercise, and might not reach aerobic glycolysis, leading to a need for rest (Schocke et al., 2008). However, lactic acid and low intracellular pH during anaerobic exercise are associated with adenosine release from skeletal muscle or endothelial cells, which, with persistent challenge, could lead to increased vascular endothelial growth factor (VEGF) production, endothelial cell proliferation, and capillary number, contributing to increased microcirculation and improved walking ability (Haas et al., 2012).

Hypoxia facilitates greater responsiveness to adenosine. Hypoxia inducible transcription factor 1α , in particular, but also hypoxia inducible transcription factor 2α and peroxisome proliferator-activated receptor γ coactivator 1α , regulate the adaptive response to hypoxia, including increased adenosine circulation, and the upregulation of VEGF. VEGFA is a factor

which could lead to proliferation of endothelial cells, mobilisation of circulating angiogenic cells, and microvascular changes. However, the degree to which hypoxia stimulates angiogenesis is unclear, and varies between tissue types, suggesting that local or intracellular factors (which may be substantially altered in chronic ischaemic conditions, like PAD) affect capillary endothelial responsiveness (Haas et al., 2012). There is limited evidence that exercise can increase circulating endothelial progenitor cells in people with IC (Schlager et al., 2011; Sandri et al., 2005), which could facilitate capillary growth or enhanced endothelial cell function.

Figure 1.2 Proposed pathway of angiogenic changes in response to exercise-induced hypoxia



VEGF, vascular endothelial growth factor.

Evidence for the development of angiogenic pathways is largely based on animal models, and there is limited research on humans, particularly people with IC. Following an acute bout of exercise, individuals with IC demonstrate higher angiostatic factors (e.g., thrombospondin-1) that inhibit VEGF-induced capillary growth, and limited increase in extracellular VEGF and messenger RNA expression of angiogenic factors compared with healthy age-matched controls, which could limit the angiogenic potential (Hoier et al., 2013).

Arteriogenesis. The enlargement of existing collateral blood vessels in response to increased blood flow, which is redistributed due to reduced downstream pressure, relies on increased shear stress combined with upregulation of key enzymes (e.g., nitric oxide, VEGF, vascular cell adhesion molecule, and fibroblast growth factor-2) that alter paracrine factors, which induce remodelling (Yang et al., 2008) (Figure 1.3). Preclinical mouse models demonstrate increased collateral blood flow, which is directly related to the intensity and duration of exercise training, and increased vessel luminal diameter in the presence of an isolated arterial occlusion (Prior et al., 2004). These adaptations are not consistently demonstrated in people with IC (Versluis et

al., 2013; De Vivo et al., 2005), possibly due to the impact of multilevel disease, which might reduce the development of an effective collateral circuit, insufficient exercise stimuli required to elicit vascular remodelling, and limitations of measures available to detect changes in collateral development and blood flow (Yang et al., 2008).

Figure 1.3 Proposed pathway of vascular remodelling resulting from changes in blood flow during exercise



FGF, fibroblast growth factor; NO, nitric oxide; VCAM, vascular cell adhesion molecule; VEGF, vascular endothelial growth factor.

Endothelial function and inflammatory markers. An important factor related to both micro- and macrovascular adaptation to exercise is endothelial function. Exercise at intensities that induce IC coincides with an acute inflammatory response and endothelial damage, but, over the long-term, may curb inflammation (Tisi and Shearman, 1998) and stimulate vascular growth factor expression, potentiating angiogenesis (Palmer-Kazen et al., 2009). A recent study including 67 individuals with IC reported a 43% improvement in flow-mediated dilation, and reduced high-sensitivity C-reactive protein concentration following 12 weeks of supervised exercise therapy (Januszek et al., 2014). However, improvement in MWA was not associated with endothelial and inflammatory markers. An RCT including 156 participants reported a MD in flow-mediated dilation of 1.5% (95% CI 0.35–2.70%) following a 24 week supervised exercise programme compared to a control group, however participants in that study had asymptomatic PAD only (McDermott et al., 2009).

Acute, ischaemia-inducing exercise is associated with increased inflammatory markers and the accumulation of reactive oxidative species in people with PAD, which may damage mitochondrial function, reduce energy production and increase apoptosis and sarcopenia. However, daily walking activity is associated with lower high-sensitivity C-reactive protein (Gardner et al., 2014) and ischaemic-reperfusion injury, including neutrophil activation and

free radical damage, was reduced following 3 months of treadmill exercise therapy in people with PAD (Turton et al., 2002), suggesting adaptations to exercise which curb the inflammatory response.

Blood rheology. Macro- and microcirculatory blood flow is affected by properties of blood rheology, including haematocrit, blood and plasma viscosity, red cell aggregation, and filterability, which are compromised in individuals with PAD compared with controls, and normalised following walking exercise therapy (Ernst and Matrai, 1987). However, the data are quasi-experimental, and included a small sample size, and the prescribed exercise therapy exceeded guidelines at two bouts of graded treadmill walking per day, on 5 days of the week over 3 months. By contrast a randomised controlled trial comparing a standard treadmill exercise programme of 3 sessions per week to pain onset found no differences in haematocrit compared with a control group, although blood lipid profiles including high- and low-density lipoprotein levels improved among those in the exercise therapy group (Mika et al., 2011).

Central cardiorespiratory fitness. Upper-limb arm ergometry exercise programmes demonstrate improvements in MWA and PFWA, suggesting a contribution of central cardiorespiratory adaptations to walking improvements, and not just local vascular and muscle adaptations to ischaemia-inducing lower-limb training (Parmenter et al., 2011). Both upper- and lower-limb exercise induced similar changes in cardiorespiratory fitness (i.e., oxygen consumption at pain onset and ventilator equivalent for oxygen uptake) which were significantly different from an inactive control, but not haemodynamic variables (e.g., blood pressure and heart rate) after 12-weeks of training, which were associated with MWA and PFWA (Bronas et al., 2011).

Skeletal muscle adaptations. In addition to increased blood flow and circulating metabolic enzymes, skeletal muscle adaptations include improvements in strength and endurance following walking exercise. Wang et al. (2006) demonstrated increased calf muscle peak force, total work, and power following 12 weeks of treadmill exercise in individuals with stable IC;

changes in peak force correlated with increased MWA ($r=0.63$, $p<0.01$) and PFWA ($r=0.53$, $p<0.05$).

Gait alterations and walking economy. People with IC demonstrate greater variability in gait, longer stance time, and increased ground reaction force compared with healthy controls before and after the onset of symptoms during walking (Myers et al., 2011; Scott-Pandorf et al., 2007). Reduced walking speed and efficiency in people with PAD leads to increased oxygen demand. There is limited evidence for changes in gait kinematics following walking exercise (King et al., 2012), although reduced oxygen consumption at submaximal workload following training suggests improvements in overall walking economy (Milani and Lavie, 2007).

1.7.6 Supervised versus home-based exercise therapy

Evidence supporting walking treatment for IC is largely drawn from research on supervised exercise therapy, which is typically centre-based, structured and conducted on treadmills or a walking track (Watson et al., 2008). While supervised exercise therapy is a cost-effective treatment for IC (Treesak et al., 2004; Ambrosetti et al., 2004; Bermingham et al., 2013), programmes can be resource- and time-intensive, and are not widely available (Stewart and Lamont, 2001; Norgren et al., 2007). The estimated cost for initiating a physiotherapist-led supervised exercise programme in the NHS is £255 per person, and is a key barrier to implementation (NICE, 2014b). Only 24% of vascular surgeons in the UK have access to programmes which they could refer individuals with IC to, and the majority of available programmes are available only on 1 day per week, and so do not meet recommendations for IC management (Shalhoub et al., 2009).

Due to the limited availability of supervised exercise therapy, individuals with IC often receive simple “go home and walk” advice (Makris et al., 2012) from a clinician (Stewart and Lamont, 2007; Shalhoub et al., 2009). Content and detail of walking advice varies between vascular specialists (Makris et al., 2012; Bartelink et al., 2004); in a survey including 378 vascular surgeons, predominantly from the UK, 30% reported provision of general advice to people with IC, and just 42.9% communicated specific instructions on the volume or intensity of

walking (Makris et al., 2012). Individuals with IC who recall walking advice are more likely to report walking; however, fewer than one-half and one-quarter achieved the optimal walking intensity and duration, respectively (Bartelink et al., 2004). Participants report a lack of specific walking advice as a barrier to initiating self-directed walking (Bartelink et al., 2004). Other barriers to walking identified among individuals with IC include a perceived lack of time, feeling tired, the need to stop and rest, and uneven walking terrain (Galea et al., 2008). Over 6 months, walking advice is less effective than supervised exercise therapy in improving walking ability (Fokkenrood et al., 2013).

Structured home-based exercise programmes could bridge the gap between supervised exercise therapy and walking advice. A narrative systematic review of 17 studies (10 RCTs and 7 observational) including 1457 participants, supported structured home-based exercise for improving walking ability compared with baseline performance (n=7 studies) or usual care (n=5 studies), although supervised exercise therapy was superior (n=6 studies) (Al-Jundi et al., 2013). However, components of interventions varied and were poorly reported, so the mechanisms underpinning effective interventions cannot be determined. Also, treatment fidelity was not reported, including adherence to home-based exercise, which may impact intervention effectiveness. Finally, programmes were typically delivered by a researcher, although some reported delivery by a vascular specialist (e.g., nurse), exercise physiologist, or psychologist, but none described the training or experience of the professional delivering the intervention in behaviour-change methods. By contrast with clinical practice, few interventions were delivered by a physiotherapist, despite exercise prescription, health promotion, and an understanding of psychosocial factors that influence health behaviour, forming the scope of practice of physiotherapists (Health and Care Professions Council, 2013).

A Cochrane review including 14 RCTs (n=1002 participants with IC) found greater effects of supervised exercise therapy on maximal (0.48, 95% CI 0.32 to 0.64) and pain-free walking ability (0.52, 95% CI 0.35 to 0.69) at 6-month follow-up compared with walking advice and structured home exercise (Fokkenrood et al., 2013). Risk of bias was generally low across studies, with the exception of blinding of participants; however, treadmill walking outcomes

were reported, and so a training effect favouring supervised exercise therapy cannot be ruled out, and only four studies evaluated adherence (i.e., the dose of exercise completed), which could affect walking ability.

Gommans et al. (2014) also demonstrated superior effects for supervised exercise therapy, when compared with home-based exercise therapy, walking advice or a no-exercise control on maximal and pain-free walking ability at 6 weeks and 3 months in a meta-analysis of 30 studies (n=1406 participants with PAD). However, there was no difference between supervised exercise therapy and home-based exercise therapy at 6-month follow-up suggesting that either any effects of supervised, treadmill-based therapy were lost following programme discontinuation or that maintenance of home-based exercise therapy was superior or its effects occurred at a slower rate.

In summary, home-based exercise therapy results in improvements in walking ability from baseline and greater improvements compared with walking advice alone. The effectiveness of supervised exercise therapy compared with other treatments may be diminished over the long-term.

1.8 Conclusions

- IC is a prevalent symptom of atherosclerotic PAD, associated with reduced walking ability, physical function, and health-related quality of life.
- Supervised centre-based exercise therapy is an effective recommended treatment for IC, but is limited in availability, and relies on adequate attendance and adherence to self-directed walking post-discharge, which has not been demonstrated.
- Home-based exercise therapy may be a viable, low-cost alternative to supervised exercise therapy, but evidence is based on low quality data, including poorly defined interventions which may not reflect practice.

Chapter 2. Theory-based behaviour change and adherence to walking with IC

Participation in both supervised and home-based exercise programmes require the individual to change their behaviour, for example by adopting a new regimen or changing their current exercise volume or intensity. Initial and continued behaviour change is crucial to the effectiveness of all exercise programmes for IC. Yet adherence to supervised centre-based exercise programmes is variable and short-lived (Lane et al., 2014), and individuals with IC do not maintain self-directed activity (i.e., walking behaviour) following discharge from a programme (Menard et al., 2004). While guidelines recommend supervised exercise therapy for IC, in practice, home-based walking is frequently advised (Norgren et al., 2007; Stewart and Lamont, 2001; Stewart and Lamont, 2007), and may present different challenges to short- and long-term behaviour change.

Without intervention, walking behaviour and walking ability progressively declines among individuals with IC (Gardner et al., 2004), contributing to an increased risk of cardiovascular morbidity and mortality (Garg et al., 2006). While structured home-based walking may provide a viable alternative to supervised exercise therapy, adherence rates as low as 34% (Makris et al., 2012) could compromise the cost-effectiveness and commissioning of programmes (Birmingham et al., 2013). Despite being a significant problem, little is known about the factors associated with uptake or adherence to self-directed walking behaviour and improved walking ability among individuals with IC (Buck and Ciccone, 2004).

Adherence to treatment, such as walking for IC, is a complex interplay between the individual, provider, and context, which is centred on behaviour (Miller, 2012). Within the NHS (provider), an important aspect of a walking programme is “supervision”; however, the type of instructor and volume of contact varies and is not accounted for in RCTs comparing supervised and home-based walking programmes; therefore, the role and degree of supervision required, important factors related to implementation of programmes, are not clearly understood (Wind

and Koelemay, 2007; Watson et al., 2008). Sources of behaviour change related to the individual include capability (e.g., physical and psychological), opportunity (e.g., physical and social), and motivation (e.g., reflective and automatic processes) (Michie et al., 2011b), which should be targeted during interventions that promote walking for IC. Even once a regimen of walking is established, unexpected disruptions can interrupt or end previous routines (Dishman, 2001), so interventions are needed that equip individuals with the necessary skills and resources to adapt or adjust their behaviour.

Factors that may contribute toward an understanding of behaviour change and adherence to walking among individuals with IC include 1) consistent reporting of intervention components that could contribute to increased walking and 2) the use of behaviour-change theory in the development and evaluation of interventions in order to facilitate walking uptake and adherence.

2.1 Behaviour-change techniques and the systematic reporting of theory-based interventions

A standardised format and language for reporting complex interventions, such as walking programmes for IC, could support syntheses of data, facilitate replication and adoption of novel treatments, and contribute to identification of intervention components, or combinations of components, that are producing an effect (Abraham and Michie, 2008). To address the need for standardised reporting, Abraham and Michie (2008) developed a 26-item taxonomy of theory-linked behaviour change techniques (BCTs) relevant to diet and physical activity, which was subsequently expanded and refined to include 40 distinct items (Michie et al., 2011a), and again to include 93 items (Michie et al., 2013).

Items in the taxonomy target individual motivation, and range from simple tasks such as keeping a diary in order to monitor walking or setting behavioural goals, to complex psychological techniques including motivational interviewing (discussing and exploring with the individual ways to minimise resistance and ambivalence toward walking) (Rollnick and Miller, 1995) and action planning (detailed preparation of when, where and how the individual

will engage in walking) (Gollwitzer, 1999). While the taxonomy is not exhaustive, it provides a standardised classification to assist in the reporting and synthesis of data from complex interventions.

The 40-item taxonomy was applied in a review of 25 behaviour-change interventions targeting self-efficacy and physical activity (primarily walking) in healthy older adults (French et al., 2014). Overall, 29 BCTs were identified, and interventions included, on average, 8 BCTs. Treatment effects on self-efficacy ($d=0.37$, 95% CI 0.22, 0.52) and physical activity ($d=0.14$, 95% CI 0.09, 0.20) were small to medium, and large effects were moderated by the inclusion of barrier identification with problem solving, providing rewards contingent on successful behaviour, and modelling or demonstration of the behaviour. However, 10 BCTs were associated with smaller physical activity effects, and 6 with both decreased self-efficacy and physical activity. High variability across data limits the interpretation of findings, and it is impossible to determine whether BCTs were delivered consistently and with fidelity to the treatment, or to discern whether effects were dependent upon combinations of BCTs.

A review of behaviour-change interventions targeting physical activity in people with coronary artery disease identified 23 studies (Ferrier et al., 2011). Follow-up prompts, general encouragement, goal setting, and self-monitoring were techniques most frequently associated with increased physical activity following home-based programmes ($n=7$ studies). However, participants were mostly male, measures of physical activity varied and included non-validated tools, and study quality was low.

To date, BCTs applied to walking interventions for IC have not been systematically identified or evaluated.

2.2 Identifying and applying theory to behaviour-change interventions

Identifying and understanding factors that predict and explain behaviour change might provide targets for interventions, and inform the selection of appropriate BCTs to facilitate home-based walking among individuals with IC. Individual motivation is an important facet of

adherence (Michie et al., 2011b), which can be understood by exploring theory-based psychosocial variables that are proposed to influence health behaviour (Buckworth, 2000); evidence for predictive and causal links can then be applied in the design, implementation, and evaluation of interventions (Buckworth, 2000; Sutton, 2011; NICE, 2007). Both the Medical Research Council (MRC) and NICE endorse a theory-guided approach to behaviour-change interventions, and recommend the identification and assessment of psychosocial variables targeted by a programme (NICE, 2007; Craig et al., 2008). In particular, NICE proposes that interventions address individual beliefs, attitudes, intentions, skill, and knowledge associated with the target behaviour (NICE, 2007). However, there are multiple theories supporting behaviour change, considerable overlap among constructs between theories, and theories are limited in their description of the processes whereby behaviour change occurs (Abraham et al., 2009). Therefore, identifying a relevant theory and strategies for implementing the theory can be a challenge during the early stages of intervention design. Criteria for selecting a theory to underpin an intervention include the following (Sutton, 2011):

- 1) clearly defined constructs and causal relationships between constructs;
- 2) substantial empirical support, including evidence that proposed determinants influence behaviour; and
- 3) specification of how behavioural determinants can be modified.

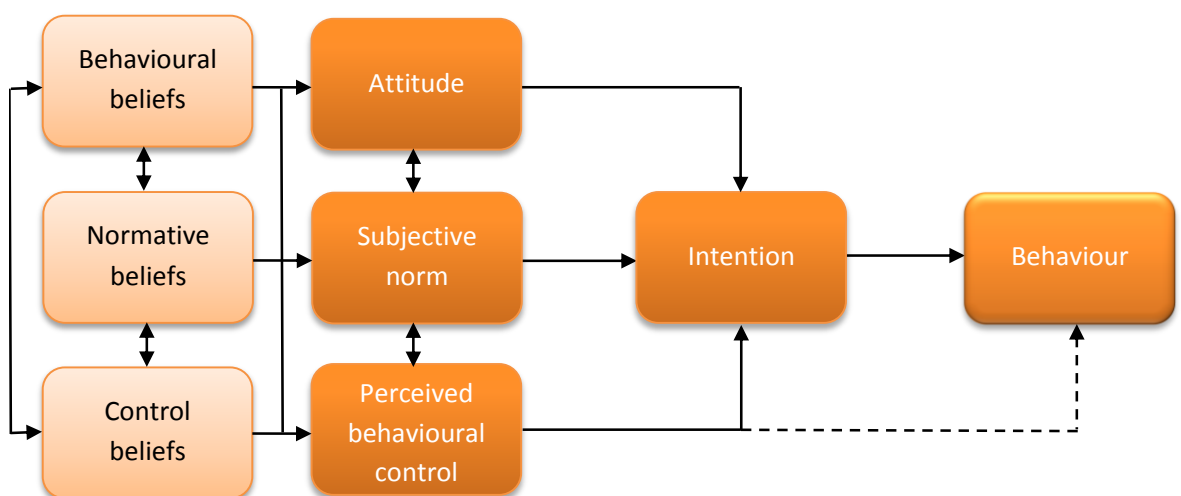
Few theories meet all criteria, and so the process of selection relies on a degree of compromise (Sutton, 2011). Two theoretical models, with clearly defined constructs and robust empirical support, are potential frameworks for underpinning an intervention to increase walking in people with IC: 1) the Theory of Planned Behaviour (TPB); and 2) the Common Sense Model of Illness Representations (CSM).

2.3 The Theory of Planned Behaviour (TPB)

The TPB (Ajzen, 1985; Ajzen, 1991) is a social cognitive model of the proximal determinants of individual motivation and behaviour, and is an extension of the Theory of Reasoned Action

(TRA) (Ajzen and Fishbein, 1980; Fishbein and Ajzen, 1975). The TPB proposes that human behaviour is inherently goal-directed, and implicit or explicit plans are prerequisites both for conscious and non-conscious behaviour enactment (Ajzen, 1985). Accordingly, *intention* is a proximal determinant of behaviour in the TPB framework. Intention represents a person's motivation, goal, or conscious plan to perform (or attempt to perform) a behaviour, and provides an indication of the willingness and effort that is likely to be applied when attempting to engage in a behaviour (Ajzen, 1988). Within the TPB literature, intention has been conceptualised as a behavioural intention (e.g., "I will"), desire (e.g., "I want"), or behavioural expectation (e.g., "I am likely to"). Behavioural intention tends to be the strongest predictor of behaviour (Armitage and Conner, 2001), and is conceptually more distinct from other constructs within the model, whereas desire and expectation may be accounted for by attitude or perceived behavioural control (Sheeran, 2002).

Figure 2.1 Schematic diagram of the Theory of Planned Behaviour (TPB)



Intention is the function of a person's attitude toward the behaviour and subjective norm, which account for volitional behaviour, consistent with the TRA (Ajzen and Fishbein, 1980; Fishbein and Ajzen, 1975). However, according to Ajzen (1985), "every intended behaviour is a goal whose attainment is subject to some degree of uncertainty" (pp. 24). Moreover, a behavioural intention is best interpreted as the intention to *attempt* to perform a behaviour,

and behavioural goal attainment is contingent on the person's perception of (and actual) control over the various factors that may prevent it (Ajzen, 1985). Therefore, perceived behavioural control is a key variable which distinguishes the TPB framework, and enables the model to account for non-volitional behaviour, such as engaging in walking treatment for IC.

Attitude, subjective norm, and perceived behavioural control are constructs defined by expectancy-value conceptualisations, which form underlying behavioural, normative, and control beliefs, respectively. The strength and saliency of these underlying beliefs are products of anticipated outcomes of performing the behaviour and the value placed by the individual on those outcomes. The constructs and their underlying beliefs are conceptually and empirically associated and, with the exception of elicitation studies, direct measures of attitude, subjective norm, and perceived behavioural control constructs are typically reported (Ajzen, 1985; Armitage and Conner, 2001).

Attitude represents an individual's positive or negative evaluation of a behaviour, and reflects the perceived likelihood of a salient outcome of performing the behaviour and the perceived value of that outcome. A person who anticipates mostly positive, valued outcomes of performing a behaviour will hold a favourable attitude toward the behaviour, and will be more likely to intend to perform the behaviour.

Subjective norm is defined as the perceived social pressure regarding whether or not to perform a behaviour. This construct reflects the perceived approval or disapproval by salient referents regarding the behaviour, and the individual's motivation to behave consistently with those referents. Individuals who believe that others with whom they are motivated to comply (e.g., a close family member, healthcare professional, or group of friends) endorse their behaviour are more likely to intend to perform the behaviour.

Perceived behavioural control represents the perceived ease or difficulty of performing a behaviour successfully, and accounts for the perceived access to necessary resources and

opportunities to perform the behaviour and potential obstacles, and the perceived power of each of those factors to facilitate or inhibit the behaviour. Individuals take into account internal and external influences of behaviour when forming control beliefs (Ajzen, 1988; Ajzen, 1985). The predictive accuracy of perceived behavioural control hinges on the extent to which an individual's assessment of internal (e.g., information, skills, emotions) and external (e.g., environmental barriers, cost) control factors is realistic and approaches actual control (Ajzen, 1985).

Perceived behavioural control has been compared to the construct self-efficacy, defined as an individual's confidence in their ability to perform a task in order to achieve a defined outcome (Bandura, 1997; Bandura, 1986). Perceived behavioural control and self-efficacy are correlated; however, TPB studies applying both constructs suggest that they are empirically distinct, and independently predict exercise and physical activity behaviour (Hagger et al., 2002b; Rodgers et al., 2008; Motl et al., 2005), although evidence is based largely on healthy populations, and may not reflect walking in people with IC. Despite their conceptual distinction, measures of perceived behavioural control frequently include items assessing confidence and controllability, potentially accounting for a degree of self-efficacy.

The relative importance of attitude, subjective norm, and perceived behavioural control in the formation of a behavioural intention can vary depending on the context and behaviour (Ajzen, 1991). In instances where volition is compromised (for example, due to personal or environmental barriers), perceived behavioural control also acts as 1) a direct determinant of behaviour wherein perceived behavioural control increases in predictive strength, relative to intention, as the extent of volitional control over the behaviour decreases; and 2) a moderator of the intention-behaviour relationship, such that greater perceived behavioural control is associated with a stronger intention-behaviour relationship (Ajzen, 1991). Meta-analyses of the TPB support a direct effect of perceived behavioural control on behaviour, however the

interactive effect of intention and perceived behavioural control has not been consistently demonstrated (Armitage and Conner, 2001; Ajzen, 1991).

2.3.1 The TPB as a framework for explaining exercise and physical activity

A comprehensive review and meta-analysis including 185 tests of the TPB reported an explained variance of 27% and 39% in intention and behaviour, respectively, with medium to large sample-weighted univariate effects of TPB constructs (Armitage and Conner, 2001). Perceived behavioural control added 2% of variance in behaviour, when controlling for intention. However, high variability was reported around the main effects, and findings reflected a range of behavioural outcomes including those not related to health.

The TPB has been applied extensively to health-related behaviour, and in particular to exercise and physical activity (Hausenblas et al., 1997; Hagger et al., 2002b; Godin and Kok, 1996; McEachan et al., 2011). In an early review, including 31 studies, attitude ($r=0.39$) and perceived behavioural control ($r=0.45$) demonstrated the largest correlations with intention, followed by subjective norm ($r=0.09$); intention ($r=0.47$) and perceived behavioural control ($r=0.45$) both demonstrated large associations with exercise or physical activity behaviour (Hausenblas et al., 1997). However, most ($n=18$) studies evaluated the TRA, and so did not report data on perceived behavioural control, and just four studies reflected clinical samples (i.e., individuals with cardiovascular disease). Also, zero-order effects of predictor variables on intention and behaviour were evaluated, ignoring the shared statistical variability across TPB constructs.

In a subsequent review, Hagger et al. (2002b) applied multivariate techniques to data from 72 studies evaluating the relationship between TPB constructs and physical activity behaviour, correcting for statistical artefacts including measurement error, sampling, and inter-correlations between variables. Path analyses demonstrated a good fit of the TPB models predicting intention ($\chi^2[3]=246.6$, $p<0.01$) and behaviour ($\chi^2[2]=15.57$, $p<0.01$). Overall, 45% of the variance in intention was explained, with the greatest contributions by attitude and perceived behavioural control ($\beta=0.40$ and $\beta=0.33$, $p<0.01$, respectively), and then subjective

norm ($\beta=0.05$, $p<0.01$). Intention ($\beta=0.43$, $p<0.01$) and perceived behavioural control ($\beta=0.15$, $p<0.01$) together accounted for 24% of the variance in physical activity behaviour. However, most data reflected younger, healthy subjects (e.g., student samples), and so findings might not reflect older adults with long-term conditions, like IC. In addition, there was high variation and heterogeneity of distributions of the correlations across studies, suggesting that there may be factors which affect the consistency of associations between studies.

McEachan et al (2011) meta-analysed data from 237 prospective tests of the TPB applied to health behaviour, including 103 reflecting physical activity. Results were adjusted for measures of past-behaviour, type of behaviour, participant age and duration of follow-up. Attitude ($r=0.51$), subjective norm (0.32), and perceived behavioural control (0.47) were associated with physical activity intention, after adjusting for sampling error. The model predicted 24% of variance in physical activity behaviour ($\beta=0.42$ and 0.11 for intention and perceived behavioural control, respectively). The inclusion of past behaviour (section 2.3.2) explained an additional 10% variance (adjusted $R^2=0.34$), was the strongest predictor ($\beta=0.038$) of physical activity behaviour, and attenuated the effect of perceived behavioural control ($\beta=0.07$), but not intention ($\beta=0.22$). Overall, the TPB was best at predicting physical activity behaviour, improved when the duration of follow-up was <5 weeks, and was not affected by participant age.

The systematic reviews described above evaluate a range of exercise and physical activity behaviours, and might not apply to decisions to engage in walking. French et al. (2013) identified seven reports of the TPB ($n=1228$) evaluating walking intention, including one study of individuals with IC (Galea and Bray, 2006). Sample weighted mean correlations for attitude, subjective norm, and perceived behavioural control were $r=0.33$, 0.30 and 0.47 (all $p<0.001$), respectively, and suggest that control beliefs might be particularly influential when planning walking. However, data on behaviour were not reported, and only one study reported a sample with long-term illness.

Overall, systematic reviews of studies applying the TPB to exercise, physical activity, and walking, suggest that perceived behavioural control may be just as important as attitude in accounting for behavioural intention. Subjective norm is frequently the weakest predictor of intention, however this could be due to the use of less reliable single-item measures. Intention is consistently the strongest predictor of behaviour, with perceived behavioural control demonstrating small but significant direct effects on behaviour when controlling for intention; applications of the TPB to walking in particular suggest perceived behavioural control may be especially salient.

2.3.2 The role of past behaviour in the TPB

Past behaviour provides an approximation of the degree to which a behaviour is routine, or habitual. Routine behaviour, formed through context-dependent repetition, shifts behavioural enactment from conscious, effortful, and goal-driven actions, toward automatic non-conscious processes that are reliant on situational cues and implicit cognitions (Sheeran et al., 2013). Past behaviour demonstrates large associations with current or future behaviour and is frequently the strongest predictor of intention or behaviour in TPB studies (Hagger et al., 2002b). There is disagreement on how past behaviour should be defined within the TPB (Ajzen, 2002b); however, the following proposals have been evaluated: 1) past behaviour, particularly behaviour frequency, is defined as an indicator of habit and has a direct causal influence on behaviour, independent of TPB variables; 2) other unmeasured variables exist which mediate the effect of past behaviour on intention and behaviour, and reported effects are therefore a result of common residual variance; or 3) past behaviour reflects temporal stability of behaviour and has no causal influence on behaviour, and should be statistically controlled to provide a true approximation of the effects of TPB variables on subsequent behaviour (Rhodes and Courneya, 2003). There is limited evidence comparing the various pathways for past behaviour to impact cognitions and behaviour within in the general TPB literature, and specifically in the context of walking among individuals with long-term conditions, such as IC;

however, data from the wider TPB literature demonstrate the importance of accounting for past behaviour when evaluating and applying the TPB model.

2.3.3 The intention–behaviour gap: proximal determinants of behaviour

The basic tenets of the TPB have been widely supported; however, systematic reviews demonstrate that the model is consistently better at explaining intention than behaviour. This lack of correspondence, in particular where positive intentions to engage in a behaviour lead to subsequent inaction, has been termed the “intention–behaviour gap” (Orbell and Sheeran, 1998). Evidence of the intention–behaviour gap is drawn primarily from observational studies; however, a report of 11 RCTs of interventions targeting physical activity (Rhodes and Dickau, 2012a) demonstrated that a large effect of behaviour-change interventions on intention ($d=0.45$, 95% CI 0.30, 0.60) translated into a small effect on behaviour ($d=0.15$, 95% CI 0.06, 0.23), and suggests an important challenge for the development of effective walking programmes.

Research has sought to identify potential moderators or mediators which might improve the intention–behaviour relationship. Rhodes and Dickau (2012b) identified 57 cross-sectional and prospective observational studies evaluating intention moderation in the domain of physical activity behaviour. The most consistent moderators were intention stability, anticipated regret, and conscientiousness; however, data were limited and heterogenous, with small numbers of studies evaluating each moderator, and a meta-analysis could not be performed. Additionally, outcomes included self-reported measures of behaviour which could inflate the intention–behaviour relationship (Scott et al., 2007), and studies included healthy individuals only limiting the applicability of findings to people with IC.

2.3.4 Self-regulatory processes and volitional control of behaviour

Research addressing the intention–behaviour gap has explored self-regulatory processes as proximal determinants of behaviour. Behaviour may be conceptualised as including two distinct and sequential processes: a motivational phase and volitional phase (Schwarzer, 2014). During the motivational phase, an individual develops an intention to change their behaviour

based on salient beliefs (e.g., behavioural, normative, and control beliefs). The volitional phase encompasses planning, action and maintenance of behaviour and requires specific strategies for execution not described within the TPB, and which reflect self-regulatory processes. According to Ajzen (2011), the ability to self-regulate represents an aspect of *actual* control over behaviour, and could therefore improve the accuracy of perceived behavioural control and the likelihood of performing a behaviour. Self-regulatory processes which have been described and evaluated within the TPB include *action planning* and *action control*.

Action planning is a BCT that involves detailed planning of a behaviour, including when (e.g., frequency and duration), where, and/or the situation in which a behaviour will be enacted (Michie et al., 2011a; Leventhal et al., 1965). This prospective, self-regulatory process involves activation of a mental representation of a behaviour, prompting the individual to consider the sequence of actions required in order to achieve a complex behaviour, such as walking, and to recognise opportunities to act (Sniehotta et al., 2005b; Gollwitzer, 1999). Action planning may be particularly salient when initiating a behaviour (Gollwitzer, 1999), and increases the likelihood of a behaviour by automatising behaviour, and thereby reducing deliberation when an opportunity to engage in the behaviour arises. Thus, a shift is made from conscious, effortful control over behaviour toward automatic control determined by situational cues (Gollwitzer, 1999). Interventions targeting action planning demonstrate a small to medium effect (standardised MD=0.31, 95% CI 0.11, 0.51) on physical activity, and a maintained effect over 12 weeks (standardised MD=0.24, 95% CI 0.13, 0.35) (Belanger-Gravel et al., 2013). In an extended TPB model, action planning independently (OR=3.37, 95% CI 1.04, 10.95) distinguished attenders from non-attenders of community-based cardiovascular rehabilitation ($R^2=0.36$, $p<0.001$), alongside intention and perceived behavioural control (Sniehotta et al., 2010). Action planning predicted self-reported exercise ($\beta=0.28$, $p<0.01$) at 4 months following outpatient cardiovascular rehabilitation, and fully mediated the effect of intention on exercise in a sample of 307 individuals (Sniehotta et al., 2005a). However, the model did not account for past exercise behaviour. Action planning made only a small ($\beta=0.10$), non-significant

contribution to 4-month self-reported physical activity (total $R^2=0.20$) among 352 individuals with coronary artery disease, controlling for age, physical activity, and intention (Sniehotta et al., 2005b). However, participants reported high levels of physical activity, and action planning is proposed to be most salient when initiating behaviour. Findings therefore may not generalise to populations who are physically inactive, such as those with IC.

Action control is the conscious self-regulation of behaviour change comprising three distinct processes: awareness of standards, self-monitoring and self-regulatory effort (Karoly, 1993; Sniehotta et al., 2006). Two longitudinal studies provide evidence that self-regulatory processes may support the translation of intention to behaviour. de Bruin et al. (2012) employed bootstrapping to demonstrate that self-monitoring and self-regulatory effort at least partially mediated the relationship between intention and 3-month self-reported vigorous physical activity in 499 healthy adults. The mediating effect was maintained after controlling for significant covariates, including past behaviour, self-efficacy, and gender. However, awareness of standards was not assessed, and the sample was biased to participants who were more educated, younger, and had higher self-efficacy at baseline compared with those who were lost to follow-up, limiting the external validity of findings. Action control predicted change in intention and self-reported physical activity over 6 weeks in 122 individuals discharged from an outpatient cardiovascular rehabilitation programme (Sniehotta et al., 2006). In particular, self-monitoring and self-regulatory effort were modifiable constructs, whereas awareness of standards was unchanged over the assessment period. Findings may be particularly relevant when facilitating home-based exercise following a supervised centre-based programme.

The TPB is a viable behaviour-change framework, which has been evaluated in the context of exercise, physical activity, and walking. Attitude, subjective norm, and perceived behavioural control explain intention, whereas factors bridging the intention–behaviour relationship, including self-regulatory processes, require further exploration. The TPB defines cognitions

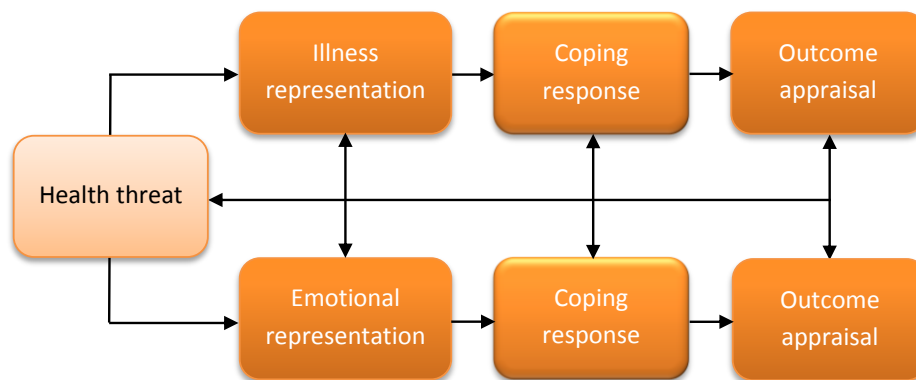
pertaining to a behaviour (e.g., engaging in walking treatment for IC). Among individuals with long-term conditions, such as PAD, cognitions reflecting their illness may also contribute to an understanding of behaviour-change, and are defined by the CSM.

2.4 The Common Sense Model of Illness Representations (CSM)

The CSM (Leventhal et al., 1980; Leventhal et al., 1984) (Figure 2.2) was developed from research describing the interaction between a health threat, which evoked fear or a perception of danger and an action plan, which outlined a behavioural coping strategy to reduce that threat. Individuals who were exposed to a health threat and provided with an action plan for coping with the threat were more likely to engage in the coping behaviour compared with individuals who were not exposed to the threat (Leventhal et al., 1965). Assumptions underlying the evolving theory were: a) that people are motivated to avoid and reduce health threats and b) that people are active, self-regulating problem solvers with regard to their health.

A health threat is established and shaped by at least three sources: a) somatic stimuli (i.e., symptoms); b) information based on past experience of illness; and c) information provided by various media and social sources, including family, friends and healthcare professionals (Leventhal et al., 1980). Information forming a health threat is processed cognitively as perceived representations of danger and emotionally as representations of fear. The integration of information is hierarchical, occurring at both concrete and abstract levels, such that individuals identify their illness by symptoms (e.g., leg pain) and by labels for those symptoms (e.g., “intermittent claudication”) through an iterative process to form an implicit, personal, common sense model that defines their illness (Leventhal et al., 1980).

Figure 2.2 Schematic diagram of the Common Sense Model of Illness Representations



Self-regulation is a key process underlying the CSM, and comprises the processes of action planning and action control (Section 2.3.4). According to Leventhal et al. (2003), in the context of a health-related behaviour, such as walking treatment for IC, what is being regulated is the physical being and functional resources of the self, in the pursuit of identified goals. An illness representation is essential to the self-regulation of behaviour as it comprises the goals for danger or fear control, strategies for control, the criteria for appraising success and ongoing perceptions of response efficacy (Leventhal et al., 2003; Leventhal et al., 1984). For example, an individual with IC might reduce walking to avoid or minimise pain, or seek further advice or treatment.

The CSM is a parallel processing model, wherein cognitive and emotional processes can be developed simultaneously and independently, but can interact with one another such that emotional reactions can impact perceived symptoms, coping, and the evaluation of coping responses (Leventhal et al., 1984). Cognitive representations of the illness can generate an emotional response, based on the abstract label of the illness (e.g., narrowed arteries) and the concrete features (e.g., leg pain, cold feet) (Leventhal et al., 1984). Throughout the self-regulatory process individuals actively evaluate the efficacy of action plans and coping

strategies and incorporate this information to their illness representation, which may therefore develop and change over time.

2.4.1 Components of illness representations

Leventhal et al. (1984) described at least four attributes which comprise an illness representation, and which mediate the relationship between a health threat and coping response (Figure 2.2). These include identity (i.e., the abstract label given to the disease and concrete symptoms that define the illness, such as “IC” or “leg pain”), timeline (i.e., the extent to which the illness is perceived as acute, episodic [recurrent] or chronic), consequences (i.e., the perceived severity of the illness and possible impact on physical, social and psychological functioning), and cause (i.e., the extent to which the cause of illness is attributed to personal or external factors). The components of an illness representation have been refined psychometrically to incorporate illness coherence (i.e., a meta-cognition representing the individuals understanding of their illness and the plausibility of their illness representation), and perceptions about control and cure of illness, initially reflected by a single construct (“control/cure”), then distinguished as personal control (i.e., the perceived confidence in one’s ability to control their condition), and treatment control (i.e., the perceived efficacy of health advice or treatment), respectively (Moss-Morris et al., 2002).

2.4.2 The CSM, coping responses, and illness outcomes

Research on the CSM has focused on the relationship between illness representations and coping responses, and has explored a range of psychosocial, functional and behavioural health outcomes associated with illness.

In a meta-analysis of 45 observational studies of illness representations reflecting 23 illnesses, higher illness identity, perceived consequences and chronic timeline were associated (range $r=0.12$ to 0.23 , $p<0.05$) with maladaptive coping strategies (e.g., avoidance/denial and expressing emotions), whereas perceived control or cure for illness was associated ($r=0.12$ to

0.27, $p < 0.05$) with adaptive coping strategies (e.g., cognitive reappraisal, problem-focused coping and seeking social support) (Hagger and Orbell, 2003). Identity and consequences were inversely associated ($r = 0.18$ to 0.67 , $p < 0.05$) with health outcomes (e.g., physical functioning, psychological well-being, role functioning, social functioning, vitality, and lower psychological distress), while chronic timeline and control/cure were positively related ($r = 0.11$ to 0.24 , $p < 0.05$). Few studies evaluated exercise or physical activity as a behavioural coping strategy, or objective measures of physical functioning, and no studies included people with IC. Additionally, high error variance could not exclude the possibility that moderating variables accounted for many of the associations observed. Finally, causal attributions, coherence, and emotional illness representations were not evaluated.

2.4.3 The CSM as a framework for explaining exercise and physical activity

The CSM has been applied in the context of supervised exercise therapy for cardiovascular and cardiopulmonary diseases. A systematic review of eight cross-sectional and prospective correlational studies, including 906 individuals with newly diagnosed coronary artery disease, suggested a greater illness identity, and more positive beliefs about consequences, cure or control, and coherence predicted attendance at cardiovascular rehabilitation (French et al., 2006). Effect estimates were small (range $r = 0.084$ to 0.160), and only cure or control had a significant effect on attendance after correcting for measurement error and unequal numbers of attenders versus non-attenders. Causal attributions were not evaluated due to measurement inconsistencies and lack of data, and attendance at rehabilitation, which provides a surrogate measure of exercise adherence, was defined as “at least one session” in seven studies and “at least 50% of sessions” in one study, and thus may not reflect regular exercise participation that achieves the recommended dose for health benefits (Department of Health, 2011).

A prospective, observational study including 96 individuals with chronic obstructive pulmonary disease (COPD) explored the effect of baseline illness cognitions on 6MWD following pulmonary rehabilitation (Zoeckler et al., 2014). A composite illness representation was

evaluated, and reflected the sum of scores obtained for illness perception constructs on the Revised Illness Perception Questionnaire (IPQ-R) (Chapter 3), a 70-item scale which demonstrates test-retest reliability up to 6 months, and is validated in populations with acute and chronic illness (Moss-Morris et al., 2002). Baseline illness representations explained 12% of variance in 6MWD ($\beta=-0.43$, $p<0.05$), after controlling for age, gender, depressive symptoms, anxiety, COPD severity, and baseline 6MWD (R^2 adjusted=0.77, $p<0.01$). Perceptions of COPD as cyclical and acute, and a negative emotional response were correlated with shorter 6MWD, but no associations with positive illness perceptions were found. Causal attributions and illness identity were not evaluated, which are important constructs defined by the CSM, and although the composite illness representation scale had good internal consistency (Cronbach's $\alpha=0.82$), further psychometric properties were not reported, and the small sample size meant the study may not have been powered to evaluate effects of independent constructs.

2.5 The TPB and CSM applied to interventions targeting exercise and physical activity

Despite its utility for explaining and predicting exercise and physical activity, the TPB lacks explicit instruction on how to modify variables and change behaviour, and therefore its suitability for intervention development has been questioned (Sutton, 2002). However, a review identified 24 TPB interventions across a range of health behaviours, which demonstrated small effects on intention and behaviour. Among studies which applied the TPB during the intervention development, 42% and 33% reported an effect on intention and behaviour, respectively (Hardeman et al., 2002). BCTs included providing information, persuasion, goal setting, skill rehearsal, modelling, planning and implementation, and social support. Most studies included TPB variables as outcomes, but did not apply the TPB to develop the intervention or assess change in TPB cognitions. In addition, few studies targeted individuals with or at risk for long-term illness, among which none addressed exercise or physical activity behaviour.

Two subsequent trials draw on the TPB systematically to develop exercise or physical activity interventions. The ProActive trial evaluated a behaviour-change intervention targeting TPB cognitions and volitional processes (Williams et al., 2004) that aimed to bridge the intention-behaviour gap in order to increase physical activity among sedentary individuals at risk for type II diabetes mellitus. BCTs included goal setting and review, action planning, self-monitoring, follow-up prompts, and reinforcement. Compared with a brief information leaflet promoting physical activity, both face-to-face and telephone-delivered versions of the intervention were unsuccessful at increasing 12-month physical activity measured by objective heart rate monitoring (Kinmonth et al., 2008). In addition, the intervention arms demonstrated only small effects on attitude, perceived behavioural control, and intention to increase physical activity at 6 months (Hardeman et al., 2009). Data on fidelity of treatment delivery indicated that only one-half of BCTs were applied by intervention facilitators, which may explain these results.

Darker et al. (2009) evaluated a TPB intervention including a motivational phase that targeted control beliefs and self-efficacy to engage in walking, and a volitional phase applying goal setting, action planning, and coping planning strategies in a cross-over waiting list study. The intervention had a large effect ($d=0.90$; mean 19.8 to 32.2 minutes/day of walking) on pedometer walking 1 week post-intervention, and behaviour was higher at 6 weeks versus baseline in sedentary adults. The effect of the intervention on intention was mediated in part by perceived behavioural control and attitude, and the effect on behaviour was mediated by perceived behavioural control, but not intention or action planning. However the study design limits the between-group comparisons at follow-up.

Both studies demonstrate the feasibility of applying the TPB to interventions, but draw on multiple theories to enlist behaviour-change strategies. For example, Darker et al. (2009) incorporated self-efficacy, and used BCTs described by Social Cognitive Theory, including past performance and mastery experiences. The ProActive trial was underpinned by the Self-Regulation Theory, Operant Theory, and Relapse Prevention Theory (Hardeman et al., 2009).

Finally, both studies targeted sedentary at-risk populations, and conclusions cannot be drawn about the application of TPB interventions in individuals with established, long-term conditions, such as IC.

The CSM has been applied less extensively to interventions targeting exercise and physical activity. A brief inpatient intervention, comprising four individual 30 minute sessions based on the CSM, and delivered by a health psychologist increased return to work, illness coherence, accuracy of causal attributions, intention to attend cardiovascular rehabilitation, and self-reported strenuous physical activity at 3 and 6 months among participants following a cardiovascular event (n=52) compared with a usual care group (n=51) (Broadbent et al., 2009). However, physical activity was not measured by a validated tool nor was it explicitly targeted by the intervention, and so the effect on physical activity may be attributable to processes other than those proposed by the CSM.

While research has evaluated TPB- or CSM-based interventions for increasing exercise or physical activity, findings are equivocal, and there is limited research specifically evaluating their effects on walking, and particularly among individuals with IC, described below.

2.6 The TPB and CSM applied to walking among individuals with IC

The TPB has been applied to two studies evaluating walking among individuals with IC. In both studies, attitude, subjective norm, and perceived behavioural control predicted 67% of variance in walking intention (Galea and Bray, 2007; Galea and Bray, 2006). However, the utility of the model for predicting walking behaviour was mixed. In one study perceived behavioural control explained 8% of variance in prospective self-reported walking behaviour during the upcoming week with no contribution by intention (Galea and Bray, 2006), suggesting an intention–behaviour gap. Potential mediators of the intention–behaviour relationship were not explored in these participants who were predominantly conservatively managed, and so findings might not reflect the wider population of people with IC.

In the second study, 34% of variance in self-reported walking behaviour during the upcoming 4 weeks was explained by both intention and perceived behavioural control, providing support for the full TPB model. The increase in variance explained may be because the measure of walking frequency and duration was obtained from a validated physical activity scale (Physical Activity Scale for the Elderly [PASE]) (Washburn et al., 1993) and combined with a longer measurement period, which may have provided more accurate data on walking. However, past walking behaviour was not assessed, which could attenuate the effect of TPB variables on future behaviour (McEachan et al., 2011).

The CSM might further explain walking, but has not been widely researched among people with IC. Cunningham (2010) assessed illness cognitions using the Brief Illness Perceptions Questionnaire, a 9-item measure which demonstrates 6 week test-retest reliability and concurrent validity with the IPQ-R (Broadbent et al., 2006; Moss-Morris et al., 2002), walking personal control, and outcome expectations in 71 individuals with IC. Participants completed a single item evaluating their average frequency of walking for at least 30 minutes. Walking and illness cognitions were accurate in distinguishing those who met walking guidelines (i.e., reported walking for 30 minutes on at least 3 days of the week) from those who did not in 93.4% of cases. However, only walking personal control, a variable devised for this particular study, and akin to perceived behavioural control as defined by the TPB, emerged as a significant determinant among variables included in that model (OR 22.3, 95% CI 1.34, 369.50, $p=0.030$), and there was insufficient evidence for the utility of illness cognitions in further explaining walking behaviour. Modifications to questionnaire items to reflect participants' beliefs about their IC symptoms (i.e., "cramping leg pain"), rather than their illness may explain these findings. According to the CSM, symptoms act as a cue, leading to illness representations, coping responses and outcome evaluations of coping (Leventhal et al., 1984; Leventhal et al., 1980). Therefore, perceptions of symptoms (i.e., IC) might not capture participants' wider illness representations (i.e., PAD). Additionally, a non-validated single-item self-reported measure of walking was used as the primary outcome without prior assessment

of its psychometric properties, which may not provide an accurate estimate of physical activity (Ainsworth et al., 2012).

The CSM has been applied to one pilot RCT to promote walking behaviour in individuals with IC (Chapter 4). A brief individual intervention comprising two 60 minute sessions and two booster telephone calls delivered by a researcher increased pedometer walking behaviour at 4, 12 and 24 months (MD at 24 months 1,630 steps, 95% CI 495, 2,765), and reduced the likelihood of angioplasty or surgery (OR over 24 months 3.09, 95% CI 1.06, 9.04) compared with usual care among 58 individuals newly diagnosed with IC (Cunningham et al., 2012; Cunningham et al., 2013). However, revascularisation moderated the effect of the intervention on daily walking behaviour, suggesting that long-term effects may be dependent upon subsequent revascularisation. While the intervention improved illness identity and personal control at 4 months compared with the control group, there were no changes in other illness perceptions, and treatment fidelity was not evaluated, therefore the processes of change are unclear.

2.7 Comparison and integration of theoretical models

The TPB and CSM are widely supported models for understanding and explaining health-related behaviour. Most research on individual health behaviour change has been informed by a single theoretical model; however, observational and interventional studies have increasingly applied multiple theoretical frameworks (Noar and Zimmerman, 2005). Studies of multiple theories, allowing comparisons between models, and enabling synthesis of or differentiation between constructs across models may contribute to the progress of health behaviour research, leading to identification of the best conceptualisation of constructs and of how constructs combine and result in behaviour change (Noar and Zimmerman, 2005).

Both the TPB and CSM describe implicit and explicit cognitive processes that drive health behaviour. However, the CSM describes thoughts and beliefs pertaining to an illness, and in response to a health threat, whereas the TPB describes cognitions pertaining to a specific

behaviour, but does not explicitly account for the illness or health threat. Among individuals with long-term conditions, such as IC, both illness and walking treatment cognitions could play a role in determining health behaviour change, such as increasing walking. Existing theories incorporating illness and treatment cognitions reflecting exercise or physical activity (e.g., Health Belief Model, Protection Motivation Theory, Health Action Process Approach) are less robust compared with the TPB (Plotnikoff and Trinh, 2010) and lack evidence supporting their utility for understanding walking motivation among individuals with IC. In addition, theories define illness cognitions as perceived severity or susceptibility only, potentially failing to account for the range of illness cognitions that determine behaviour change among individuals with IC (Chapter 6). By contrast, the CSM defines illness cognitions as perceptions regarding symptomology, causality, control or cure, timeline, consequences, and coherence, and accounts for the emotional response to an illness threat, which determine a coping response, such as walking as treatment for IC. Therefore, evaluating walking treatment cognitions defined by the TPB alongside illness cognitions defined by the CSM could provide a powerful model for understanding walking among individuals with IC.

Sneihotta et al. (2010) tested a combined TPB and CSM model in people with coronary artery disease, wherein the effect of illness representations on coping was mediated by an “extended TPB model” comprising proximal TPB variables (i.e., intention, perceived behavioural control) and action planning. Cognitions were measured in the final weeks of hospital-based outpatient cardiovascular rehabilitation, and their utility to predict self-reported physical activity and attendance at a community-based cardiovascular rehabilitation programme 2 months later was examined in a series of linear and logistic regression models. Individually, both the TPB and CSM were weak predictors of physical activity, rendering the full hypothesis untenable; in a regression analysis combining constructs from both models, only perceived behavioural control (from the TPB) and timeline cyclical (from the CSM) made independent contributions to the overall model, adding just 5% of explained variance in physical activity beyond past behaviour. Furthermore only the extended TPB model correctly classified adherers (attended

at least 1 session) to community-based cardiovascular rehabilitation in a binary logistic regression, with intention and action planning providing significant independent contributions. However, the sample was small (n=95), and predominantly (73%) male, and a short version of the Illness Perceptions Questionnaire was used, which exhibited poor reliability for two subscales assessing personal and treatment control.

Leventhal (2010) suggested that both treatment and illness beliefs should be targeted in order to change behaviour; however, to date, few studies have applied the TPB and CSM together to develop and evaluate interventions. The present research will build on previous evidence, evaluating walking treatment and illness cognitions defined by the TPB and CSM, respectively, to inform the development and evaluation of a behaviour-change intervention targeting walking in people with IC.

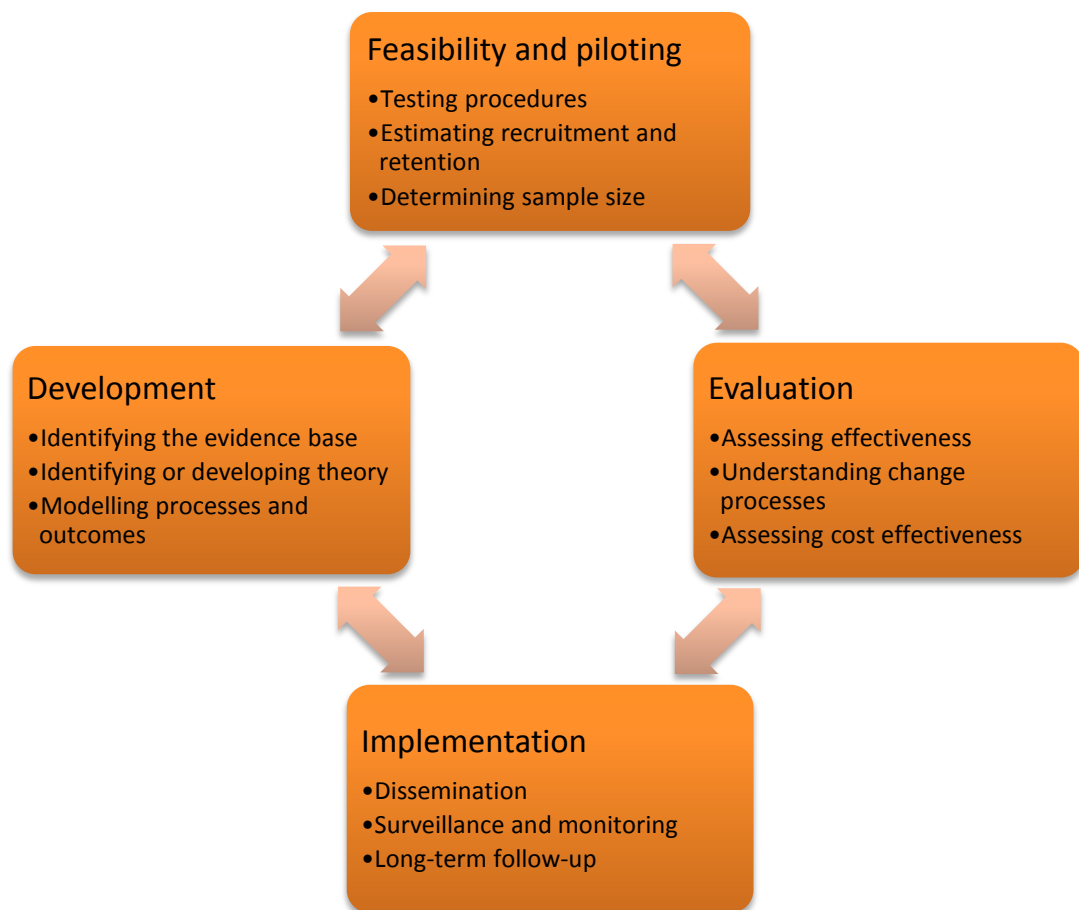
2.8 Conclusions

- BCT taxonomies may contribute to the systematic reporting, evaluation, and development of walking interventions among individuals with IC.
- The TPB and CSM are widely supported models for understanding and explaining health behaviour, including walking behaviour and ability.
- To date, the TPB and CSM have not been applied together to explain, evaluate, or facilitate walking among individuals with IC.

Thesis aims

The purpose of the current research is to develop and evaluate a physiotherapist-led behaviour-change intervention targeting self-directed walking in people with IC. MRC guidelines identify four key elements of the development and evaluation process for complex interventions (Craig et al., 2008) (Figure 3.3). Acknowledging that the process can vary in its sequence, and in the emphasis placed on various elements, the current research focuses on a) development (e.g., identifying the evidence base, identifying and developing theory) and b) feasibility and piloting (e.g., testing procedures for a definitive trial).

Figure 2.3 Key elements of intervention development and evaluation processes according to Medical Research Council guidelines



Reproduced from Craig et al. (2008) with permission from the BMJ Publishing Group, Ltd.

Thesis objectives

The objectives of this thesis are:

- a) to identify and evaluate evidence for theory-based behaviour-change techniques that have been applied walking interventions for people with IC;
- b) to explore of the experiences of and beliefs about illness and treatment among individuals with IC;
- c) to evaluate constructs defined by the TPB and CSM as determinants of walking intention and objective walking ability; and
- d) to develop and assess the feasibility and acceptability of an RCT of a physiotherapist-led home-based behaviour-change intervention targeting walking in people with IC.

Chapter 3. Selection and evaluation of methods and measures

3.1 Introduction

MRC guidelines outlining the development and feasibility testing of complex interventions, such as walking interventions for IC, recommend combining qualitative and quantitative methods to identify the evidence base, develop appropriate theory, and model processes and outcomes in advance of a definitive trial (Craig et al., 2008). This research employs a mixed-methods approach, and follows a pragmatic epistemology, wherein the method for a single study is matched to the research question, and qualitative or quantitative methods are distinct but corresponding in their overarching goal (Yardley and Bishop, 2015). A strength of using mixed-methods is the plurality of approaches, which accommodates complex research questions, and encourages creativity and adaptability in research conductance (Hesse-Biber and Johnson, 2013).

Qualitative methods applied during this thesis include:

- the Framework Method.

Quantitative methods evaluate three areas relevant to the research question and individuals with IC:

- Walking;
- Theory-based constructs; and
- Descriptive clinical variables.

Qualitative methods can be applied at all stages of intervention development and evaluation (Nastasi and Schensul, 2005; Craig et al., 2008), and can illuminate processes underpinning intervention effects, and redirect or reframe future research (Sandelowski, 2004; Speller et al., 1997). Data on the lived experiences and beliefs of individuals with IC, pertinent to walking, can generate explanatory evidence for walking behaviour, and identify processes which could

be targeted by interventions (Chapter 5). During intervention evaluation, qualitative research may reveal the processes underpinning intervention effects, determine the acceptability of the study protocol and intervention, and identify areas to address before further research or implementation (Chapter 8) (Craig et al., 2008).

Qualitative studies exploring walking in individuals with IC have applied Thematic methods to analyse and interpret data (Galea et al., 2008; Gorely et al., 2015; Cunningham et al., 2014). Thematic analysis identifies consistencies and contradictions within data, elucidates relationships across data, and draws descriptive or explanatory conclusions that cluster around themes (Braun and Clarke, 2006; Gale et al., 2013). Strengths of this approach include its parsimony and flexibility, including applicability across epistemologies and theoretical frameworks, and a balance of inductive and deductive methods. However, it has frequently been applied and reported inconsistently, and while Thematic analysis permits the use of *a priori* theory-driven codes, the guidelines for this approach are unclear (Braun and Clarke, 2006).

One approach, which has not yet been applied to research involving people with IC, is the Framework Method, which is underpinned by Thematic analysis and characterised by a systematic procedure of organising data (Ritchie and Spencer, 1994; Gale et al., 2013). The early stages of data management may be largely deductive, and permit *a priori* codes, making the Framework Method suitable for theory-driven research with predefined objectives (Pope et al., 2000), such as the current thesis. The overall process relies on rigorous interpretation to extract meaning and explanations inductively (Ritchie and Spencer, 1994). This is achieved through a reflexive process acknowledging the empirical basis of the research and the emerging, inductive outcomes of the qualitative process (Nastasi and Schensul, 2005; Gale et al., 2013).

Quantitative studies seek to understand and evaluate walking, defined as walking behaviour and walking ability. Walking can be measured objectively (e.g., pedometer, 6MWT) and by self-

report using validated questionnaires. Demonstrating that a theoretical model explains behaviour is important for theory testing and development, and therefore self-reported measures are frequently employed in that context, which are correspondent with measures of theoretical constructs (Armitage and Conner, 2001; McEachan et al., 2011). However, in applied research, generating understanding of the cognitions driving behaviour change might be better achieved by employing valid and reliable objective outcome measures. Objective measures of walking behaviour include monitoring devices, such as pedometers, which capture activity data in real time, and show better criterion validity than self-reported measures when compared with accelerometer-derived physical activity (Prince et al., 2008). It is important also to consider disease-specific and broader health outcomes of an intervention, including symptoms and health-related quality of life.

3.1.1 Aims

This chapter aims to describe and evaluate qualitative and quantitative methods and measures, including self-reported constructs and objective outcomes, applied in this research to establish a body of evidence informing a theory-based behaviour-change intervention targeting walking in people with IC.

3.2 Research Governance and Good Clinical Practice

This research recruited participants with IC from two NHS sites. The investigator (MGH) received NIHR training in Good Clinical Practice, and all research involving NHS patients was carried out in accordance with guidelines to ensure participant safety and confidentiality. Approval from a Research Ethics Committee and local Research & Development Departments across sites was received prior to studies commencing (Appendix 1). Participant Information Sheets, Participant Consent Forms, and a sample letter informing General Practitioners of their patients' participation in the research are provided in Appendix 1.

3.3 The Framework Method for qualitative research

3.3.1 Topic guide development

Qualitative topic guides were developed following recommendations consistent with the Framework Method (Ritchie and Spencer, 1994; Gale et al., 2013) and used to guide semi-structured audio-recorded interviews. Topics established *a priori* were addressed (e.g., treatment and illness beliefs, acceptability of treatment), which were consistent with the theoretical objectives of the research, but questions were open to enable new topics and themes to emerge from participant accounts (e.g., “What is it like having PAD?”). Topic guides were pilot tested, and refined iteratively following early interviews.

3.3.2 Procedure

Participants were invited to individual semi-structured interviews conducted by one researcher (MGH). Interviews took place at King’s College London (London, UK) (Chapters 5 and 8) or at participants’ homes (Chapter 5) if they preferred. Interviews were audio-recorded and followed a topic guide.

3.3.3 Qualitative data analyses

Key stages of the Framework Method for analysing qualitative data were applied (Table 3.1). Interviews were transcribed verbatim and analysed using NVivo 9 (QSR International Ltd, Southport, UK). Accuracy of transcripts was checked against the original recordings. Familiarisation took place during transcription, reading, and review of transcripts. Recurrent themes, including those reflecting *a priori* topics (i.e., illness and treatment beliefs) and emergent topics raised by participants (i.e. pain beliefs) were recorded and incorporated to the thematic framework, which is a hierarchical index of themes and subthemes used to code data. The thematic framework was then used to index, or code, the transcribed data. Results were charted in a case-by-category grid used to summarise, view, and analyse the data. Descriptive and explanatory patterns were identified and used to develop a thematic map explaining relationships between the superordinate themes and subthemes.

Table 3.1 Stages of the Framework Method for analysing qualitative data

Stage	Description
Transcription	A verbatim transcription of the audio-recorded data is produced, allowing initial immersion of the researcher with the data.
Familiarisation	Further immersion in the raw data by listening to audio-recordings, reading transcripts and studying notes taken during interviews. Key ideas and recurrent themes are listed.
Coding	Line-by-line coding of transcripts by applying open (e.g., emerging from the data) or predefined (e.g., based on existing theory or research question) categories to data to facilitate systematic comparisons across the data set.
Development of the analytical framework	A coding system, or tree, is developed from initial transcripts. This should include a category “Other”, to accommodate data that do not “fit” the evolving framework. Several iterations may be required and continued development may take place when applying the analytical framework.
Application of the analytical framework	The analytical framework is applied to all subsequent transcripts, to index data into existing categories and codes. The framework is only complete once the final transcript is coded.
Charting data into the framework matrix	A matrix is generated (typically arranged as code × participant), and charted data are reduced from verbatim text to distilled summaries retaining the meaning of participants’ views and experiences.
Interpretation of data	Charted data are explored, to define concepts, and map the range and nature of phenomena. Typologies, descriptions, relationships and causal explanations may be generated from themes identified in the data.

Adapted from Gale et al. (2013).

3.3.4 Qualitative data validation

Data were member-checked with participants to support the resonance of findings, by summarising key topics discussed with the participant immediately upon completion of the interview. Reflexive diaries and field notes were maintained for each interview. Transcripts were read by two researchers for familiarisation. The initial coding, development, and

application of the analytical framework, charting, and interpretation of data were conducted by one investigator, and reviewed and discussed by at least one other investigator in order to reach a consensus. A third researcher was available to resolve disagreements. Interpretation was considered until agreement was reached that the final themes accurately and meaningfully reflected the interview data.

3.4 Quantitative methods and measures

Measures included in this thesis are listed in Table 3.2.

Table 3.2 Outcome measures included in the thesis, reflecting walking, theory-based constructs, and descriptive clinical variables of individuals with intermittent claudication (IC)

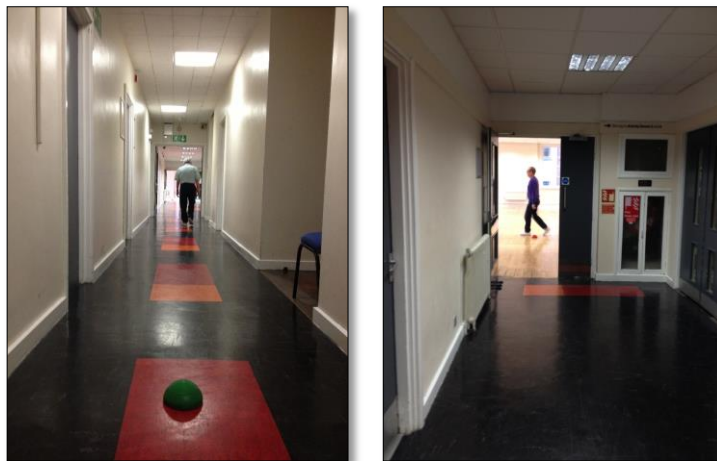
Parameter	Measure
Objective walking ability	
6 Minute Walk Distance (6MWD)	6 Minute Walk Test (6MWT)
Pain-Free Walking Ability (PFWA)	6MWT
Maximal Walking Ability (MWA)	6MWT
Walking behaviour	
Objective walking behaviour	Pedometer step count
Self-reported walking behaviour	Baltimore Activity Scale for Intermittent Claudication (BASIC)
Past walking behaviour	International Physical Activity Questionnaire (IPAQ)
Theory-based constructs	
Walking treatment cognitions	Theory of Planned Behaviour (TPB) Questionnaire
Illness cognitions	Revised Illness Perception Questionnaire (IPQ-R)
Barrier self-efficacy	Barrier Self-Efficacy Scale for Intermittent Claudication (BSES)
Action Planning	Action Planning Questionnaire
Action Control	Action Control Questionnaire
Descriptive clinical variables	
Lower-limb symptom classification	San Diego Claudication Questionnaire (SDCQ)
Health-related quality of life	Medical Outcomes Survey Short Form-12 version 2 (SF-12v2)
Perceived activity intensity	Borg Rating of Perceived Exertion (RPE)
Perceived pain intensity	Borg Category–Ratio 10 Scale for Pain (CR10)
Body mass index (BMI)	Standard scales

3.4.1 Objective walking ability

6 Minute Walk Test

The 6MWT is a submaximal exercise test, and was carried out according to a standardised protocol, including a script for instructions and feedback (Montgomery and Gardner, 1998; American Thoracic Society, 2002) (Appendix 2). Two cones were placed 30.48 metres (100 feet) apart, creating a 60.96 metre (200 foot) circuit in a straight corridor located at King's College London (London, UK). Participants were asked to walk along the corridor around the cones, and were instructed that the aim was to cover the greatest distance possible in 6 minutes. They were instructed to stop and rest if needed, but to resume walking after a self-determined rest break if there was time remaining. The researcher (MGH) stood at one end of the corridor with a stopwatch, clipboard, and 6MWT worksheet (Appendix 2). Instructions and feedback (provided every minute) followed a standardised script (Appendix 2). A marker was placed at the point along the corridor where the participant stopped walking, and the distance was obtained using a tape measure (Figure 3.1).

Figure 3.1 Participants completing the 6 Minute Walk Test



Images acquired and used with participant permission.

To optimise coordination and stride length, minimise anxiety, and to address the possibility of a learning effect (American Thoracic Society, 2002), the 6MWT was repeated during the cross-sectional study (Chapter 4). The first test was considered as a practise test, and data from the

second test were used for analyses. A minimum of 20 minutes duration was maintained between tests, to allow rest from fatigue and IC, which is the primary limiting factor of walking performance and is typically relieved within 10 minutes of rest.

The 6MWT provided three outcomes: the 6MWD, PFWA, and MWA.

6 Minute Walk Distance (6MWD)

The 6MWD is the total distance walked in metres during the 6MWT (Lipkin et al., 1986), and measures objective walking ability. The 6MWD has demonstrated test–retest reliability up to 2 weeks among individuals with IC ($r=0.94$, coefficient of variation 10.4%; intraclass correlation coefficient [ICC] 0.90, $p<0.001$), and concurrent validity with the ABPI ($r=0.55$, $p<0.001$) (Montgomery and Gardner, 1998; McDermott et al., 2008). Criterion validity of the 6MWD against accelerometer-derived physical activity level and a standardised graded treadmill test was demonstrated by linear trends across quartiles of both measures (both $p<0.001$) in 156 individuals with IC, controlling for age, gender, and race (McDermott et al., 2008). The 6MWD was sensitive to change following 6 months of combined supervised and home-based walking exercise therapy among people with IC (MD 53.5 metres compared with a control group) (McDermott et al., 2013b). The minimal clinically important difference (MCID) for the 6MWD has not been established in people with IC; however, among individuals with coronary artery disease and COPD, MCIDs are 23 and 25 metres, respectively, following exercise rehabilitation (Holland et al., 2010; Gremeaux et al., 2011).

Pain-Free Walking Ability (PFWA)

The PFWA is the distance or duration of walking before the perceived onset of IC. During the 6MWT, participants were asked to indicate the onset of leg pain either verbally or by raising one hand, whichever they preferred, and the time elapsed (in seconds) was recorded. PFWA demonstrated good test–retest reliability during corridor and treadmill walk tests (ICC 0.68–0.90, coefficient of variation 19.8–31.3%) (Zwierska et al., 2004), and the PFWA achieved during a treadmill test was moderately correlated with 6MWD ($r=0.35$, $p=0.007$) (Montgomery and Gardner, 1998).

Maximal walking ability (MWA)

The MWA represents the distance or duration of walking before IC causes the individual to stop and rest. During the 6MWT, MWA was recorded as the time elapsed (in seconds) when the participant stopped to rest for any reason before 6 minutes. MWA demonstrated good test–retest reliability during corridor and treadmill walk tests (ICC 0.81–0.87, coefficient of variation 16.4–22.4%) (Zwierska et al., 2004). During treadmill testing, the MWA was more reliable compared with the PFWA, and demonstrated greater reliability at higher workloads (Degischer et al., 2002). The MWA achieved during a graded treadmill test was moderately correlated ($r=0.53$, $p<0.001$) with 6MWD (Montgomery and Gardner, 1998).

3.4.2 Walking behaviour

Objective walking behaviour

Mean daily step count over a period of 6 days was assessed by pedometer (Omron Walking Style Pro 2.0; HJ-322U-E, Omron Healthcare UK, Ltd., Milton Keynes, UK) (Figure 3.2). The model employed uses a tri-axial accelerometer sensor as a mechanism for detecting movement. The device does not indicate periods of non-wear, which is associated with the validity of step counts, and therefore limits the interpretation of data. Data could be coupled with participant-reported wear time or a minimal acceptable wear time or step-count established as a threshold for including and analysing data (Schmidt et al., 2007).

Figure 3.2 The Omron Walking Style Pro pedometer



HJ-322U-E; Omron Healthcare UK, Ltd., Milton Keynes, UK.

Participants were instructed to wear the pedometer on their hip, on either side, ensuring it was fitted horizontally. Individual data reflecting height (centimetres), weight (kilograms), and stride length (centimetres) were input to the activity monitor for each participant to ensure the most accurate readings. To determine stride length, participants were asked to take 10

steps along a corridor, and the distance walked was marked and measured in order to compute the stride length in cm:

$$\text{Stride length (cm)} = \frac{10 \text{ step walk distance (cm)}}{10}$$

Pedometer reliability

The test–retest and criterion reliability of the Omron Walking Style Pro (HJ-720IT0-E2) was evaluated by determining the agreement between consecutive measures around a 60.96 metre level circuit and against visual step counts, respectively.

Methods

Participants. 12 Participants with IC from a larger, cross-sectional study were recruited (Chapter 5). Sociodemographic and clinical characteristics are listed in Table 3.3.

Table 3.3 Sociodemographic and clinical characteristics of participants in a reliability study of the Omron Walking Style Pro pedometer

Variable	Value, n (%)
Age, years ^a	65 (59–71) ^a
Male gender	11 (92)
White ethnicity	9 (75)
Body mass index, kg/m ^{2a}	29 (24–33) ^a
Current or previous smoker	5 (42)
Classic intermittent claudication	7 (58) ^b

n=12. ^aData are median (interquartile range). ^bDetermined by the San Diego Claudication Questionnaire.

Procedure. A pedometer was fitted onto participants left hip, attached to the waist of their trousers, and perpendicular to the ground. Participants were asked to complete one circuit around two cones placed 30.48 metres apart, covering a total distance of 60.96 metres. They were seated for 2 minutes, after which time they repeated the walking circuit. During both tests, participants were asked to walk at a brisk pace. The researcher stood at the finish of the

walk and recorded a visual step count taken in real-time during the walk. Data from the pedometer were recorded after each test and used for analyses.

Analyses. Analyses were carried out using SPSS Statistics Software version 21.0 (IBM SPSS Statistics, Inc., Armonk, NY, USA). ICCs were calculated to explore test–retest reliability (repeatability) between steps recorded by pedometer for each walk, and agreement between pedometer and visual step count determined using two-way fixed models, determined for consistency and agreement, respectively (Weir, 2005; Shrout and Fleiss, 1979).

Bland–Altman plots were used to evaluate agreement between steps measured by pedometer and by visual count during participants’ second walk (Bland and Altman, 1986). The second walk was selected as this would account for any learning effect regarding the walking protocol and to ensure that pedometers had been positioned correctly. According to guidelines for determining agreement (Bland and Altman, 1986), the following procedure was followed:

- a) the difference between scores obtained by pedometer and visual step count was computed;
- b) the mean of scores for each participant was computed;
- c) the mean ($\text{Mean}_{[\text{difference}]}$) and standard deviation ($\text{SD}_{[\text{difference}]}$) of the difference between scores was computed;
- d) limits of agreement were computed
- e) the coefficient of reproducibility was computed.

A scatterplot was generated displaying the mean scores obtained using the two measures against the difference between pedometer and visual step count. A random pattern of data points on the scatter plot indicated low risk of systematic error or bias in scores obtained by pedometer versus visual step count.

Results

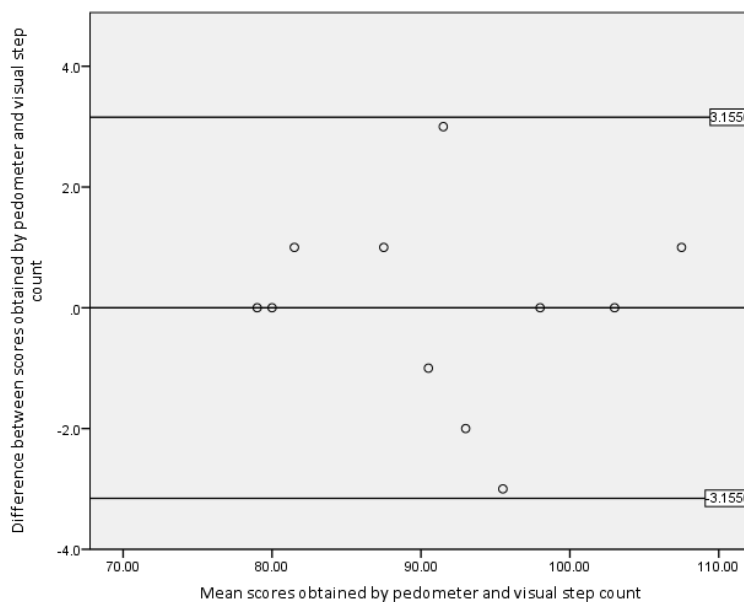
One outlier was identified during Bland-Altman analyses, which was removed.

Test–retest reliability. There was good test–retest reliability between step count on the first and second walks (ICC 0.95, 95% CI 0.83, 0.98; $p < 0.001$).

Agreement between pedometer and visual step count. There was good reliability between pedometer step count and visual step count during the first (ICC 0.97, 95% CI 0.89, 0.99; $p < 0.001$) and second (ICC 0.99, 95% CI 0.98, 0.99; $p < 0.001$) walks. These findings indicate that in both trials $< 3\%$ of variance between scores was due to random error.

A scatterplot of mean scores and difference between scores revealed no clear relationship between the mean scores and difference in means on the scatterplot (Figure 3.3). Limits of agreement indicated that for 95% of samples, step count obtained by pedometer would fall within -3.16 and 3.16 steps measured by visual count (Table 3.4).

Figure 3.3 Bland–Altman Plot illustrating agreement between pedometer and visual step count over a 60.96 metre circuit



n=11.

Table 3.4 Calculations required to generate a Bland–Altman plot for testing agreement between pedometer and visual step count over a 60.96 metre circuit

Variable	Value
Mean _(difference) ±SD _(difference)	0.0 ±1.61
Limits of agreement	-3.1556, 3.1556
Width of limits of agreement	6.3112

n=11.

Conclusions

Test–retest reliability over consecutive walks around a 60.96 metre level walking circuit was demonstrated. There was high agreement between pedometer and visual step count, demonstrating low variance due to error.

Self-reported walking behaviour

The Baltimore Activity Scale for Intermittent Claudication (BASIC) (Gardner and Montgomery, 2006) is a five-item disease-specific questionnaire assessing walking, and provides an estimate of daily physical activity level. Items are presented with three ordinal multiple choice responses, and ask participants to estimate their pain-free walking distance (0=“less than 1 block”, 1=“between 1 and 2 blocks”, or 2=“more than 2 blocks”), their behavioural response to pain during walking (0=“stop walking”, 1=“slow down”, or 2=“continue walking at the same pace”), and their frequency of walking at a fast pace, up and down stairs, and up and down hills (0=“rarely/never”, 1=“sometimes”, or 2=“frequently”). The response scale for the item reflecting pain-free walking distance was modified to reflect the estimated equivalent of walking distance in metres (0=“less than 100 metres”, 1=“between 100 and 200 metres”, or 2=“more than 200 metres”) rather than city street blocks (A Gardner, personal communication, 8 December 2011), to improve its relevance for participants based in the UK. Responses for the five items are summed to allow for scores ranging from 0 to 10, with 10 reflecting increased walking. From the total score, a continuous measure of physical activity represented in units of energy expenditure can be obtained using the following equation:

$$\text{physical activity (kcal/day)} = 102.2 + (4.96 \times \text{BASIC total score})$$

The BASIC predicts accelerometer-based daily physical activity, was sensitive to change in physical activity following a 6-month supervised exercise programme (Gardner and Montgomery, 2006), and demonstrated moderate test–retest reliability over 1 week ($\kappa=0.60$, $p=0.21$) in a small sample ($n=38$) of individuals with stable IC (Barbosa et al., 2012).

Past walking behaviour

The International Physical Activity Questionnaire (IPAQ) is a 7-item measure of daily physical activity. The self-administered short form asks participants to recall the frequency (days) and duration (minutes) of moderate and vigorous activities, walking for ≥ 10 minute bouts, and sitting over the last 7 days.

A continuous total score reflecting MET-minutes/week of physical activity is computed based on weighted durations and frequencies of reported activity per category using the following formula:

$$\begin{aligned} \text{Total activity} = & (3.3 \times \text{walking duration} \times \text{walking frequency}) \\ & + (4.0 \times \text{moderate activity duration} \times \text{moderate activity frequency}) \\ & + (8.0 \times \text{vigorous activity duration} \times \text{vigorous activity frequency}) \end{aligned}$$

where units of duration and frequency were minutes and days, respectively.

Scores for a single item reflecting walking frequency (“During the last 7 days, on how many days did you walk for at least 10 minutes at a time?”) were used in analyses to reflect past walking behaviour.

A large-scale cross-cultural study representing 12 countries including adults aged between 18 to 65 years, and including 250 participants from the UK, demonstrated test–retest reliability of the IPAQ over 1 week (Spearman’s $\rho=0.75$, $n=292$) and moderate criterion validity against accelerometer-based physical activity measured over 1 week (Spearman’s $\rho=0.40$, $n=151$) (Craig et al., 2003). Most (85%) participants in that sample were active, reporting 150 minutes/week of physical activity, and so findings may not be generalisable to individuals

who are less active, such as those with IC. However, criterion validity of the IPAQ subscales was demonstrated against accelerometer-based activity in 122 men and women aged 62 to 70 years, although test–retest reliability was low (Kolbe-Alexander et al., 2006). The IPAQ has been used in intervention studies including people with IC, and the subscale reflecting sedentary time was sensitive to change following a home-based walking programme (Cunningham, 2010).

3.4.3 Theory-based constructs

Walking treatment cognitions

A 23-item TPB questionnaire was used to assess participants' beliefs about walking treatment.

The questionnaire was adapted from a previous measure administered to individuals with IC (Galea and Bray, 2007; Galea and Bray, 2006). Instructions to participants recommended walking guidelines for people with IC to complete at least 30 minutes of walking exercise on 3 or more days per week (Gardner and Poehlman, 1995; Norgren et al., 2007). The questionnaire assesses participants' attitude (8 items), subjective norm (4 items), perceived behavioural control (7 items), and intention (4 items) regarding "the recommended walking exercise".

Items reflecting *attitude* toward walking treatment are presented on 7-point bipolar adjective scales reflecting instrumental and affective attitudes, including the following anchors: wise–foolish (reverse scored), good–bad (reverse scored), beneficial–harmful (reverse scored), useless–useful, unpleasant–pleasant, enjoyable–unenjoyable (reverse scored), boring–interesting, and stressful–relaxing.

Items reflecting *subjective norm* are presented on 7-point Likert scales ranging from 1=completely disagree to 7=completely agree, and reflect injunctive norms. One global item asks participants about important others (i.e., "Most people who are important to me think I should do the recommended walking"), whereas the remaining three items target normative referents (i.e., spouse/significant other, medical practitioner, and closest friend or family

member) identified in previous elicitation studies on individual cognitions about exercise behaviour (Downs and Hausenblas, 2005).

Items reflecting *perceived behavioural control* regarding walking treatment are assessed on 7-point Likert scales, and include one item reflecting perceived ease or difficulty (e.g., “For me to do the recommended walking exercise would be...” 1=extremely easy, 7=extremely difficult [reverse scored]), three items reflecting perceived control (e.g., “How much personal control do you believe you have over whether or not you do the recommended walking exercise?” 1=complete control, 7=absolutely no control [reverse scored]) and three items reflecting perceived confidence (e.g., “How confident are you that you will be able to do the recommended walking exercise?” 1=completely unconfident, 7=completely confident).

Items reflecting *behavioural intention* are presented on 7-point Likert scales (1=completely disagree to 7=completely agree) preceded by the statements, “I will do the recommended walking exercise”; “My goal is to do the recommended walking exercise”; and “I intend to do the recommended walking exercise”. For one item (“Do you plan to do the recommended walking exercise?”), corresponding anchors were 1=definitely not and 7=definitely so.

Scores for items representing each scale are summed and their total used for analyses. Higher scores represent more positive walking treatment cognitions.

In observational studies including people with IC, the TPB scales demonstrated internal consistency (Cronbach’s $\alpha > 0.70$), and were associated with self-reported walking behaviour ($r = 0.37\text{--}0.56$, $p < 0.05$) (Galea and Bray, 2007).

Illness cognitions

The *Revised Illness Perception Questionnaire* (IPQ-R) (Moss-Morris et al., 2002) is a three-part measure of individuals’ representation of their illness as defined by the CSM.

The first part of the questionnaire quantifies symptom identity, defined as the extent to which experienced symptoms are linked with an illness. Participants are asked to indicate symptoms

they have experienced since having their illness from a list of 14 (e.g., pain, wheezing, fatigue), and which of those symptoms are associated with their illness. Items are scored on dichotomised scales (yes/no), and the total sum of affirmative responses used in analyses to indicate identity (range from 0 to 14). Higher illness identity is associated with negative adjustment and poorer psychological and physical health outcomes (Hagger and Orbell, 2003).

The second part of the questionnaire includes 38 items assessing seven constructs reflecting illness perceptions. Items referring to “illness” were replaced with “PAD”, following guidelines for developing the IPQ-R for specific populations: acute timeline (6 items; e.g., “My PAD will last for a long time”), cyclical timeline (4 items; e.g., “I go through cycles in which my PAD gets better and worse”), consequences (6 items; e.g., “My PAD is a serious condition”), personal control (6 items; e.g., “I have the power to influence my PAD”), treatment control (5 items; e.g., “There is nothing which can help my PAD”), coherence (5 items; e.g., “I have a clear picture or understanding of my PAD”), and emotion (6 items; e.g., “My PAD makes me feel afraid”). Each item is evaluated on a 5-point scale (1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5=strongly agree). Scores for relevant items (i.e., items 1, 4, 8, 15, 17–19, 23–27, 36) were reversed, and scores for items reflecting each construct were summed, and the total used for analyses. Higher scores for personal control, treatment control, and coherence reflect positive, adaptive illness perceptions, whereas higher scores for acute timeline, cyclical timeline, consequences, and emotion reflect negative, maladaptive illness perceptions.

Using the same 5-point scale and anchors, the third part of the IPQ-R includes 18 items assessing four constructs reflecting the following causal attributions: psychological attributions (6 items; stress or worry, mental attitude, family problems or worries, emotional state, personality, and overwork), risk factors (7 items; heredity, diet or eating habits, poor medical care, my own behaviour, ageing, alcohol, smoking), immunity (3 items; a germ or virus, pollution, altered immunity) and accident or chance (2 items; chance or bad luck, accident or

injury) (Moss-Morris et al., 2002). The scale also includes an open-ended question inviting participants to list the three most important causes they believe contributed to their PAD. Scores for items reflecting each causal attribution construct were summed and the total used for analyses. Psychological and risk factor attributions reflect modifiable causes that are internal to the individual, so higher scores were defined as positive causal attributions. Immunity and accident/chance attributions reflect causes that are external to the individual, so higher scores were defined as negative causal attributions. Frequencies of each causal attribution were reported as the number and percentage of participants who responded affirmatively (i.e., “agree” or “strongly agree”) to a causal attribution item.

Summary scores for all seven IPQ-R variables and causal attributions were computed using recommended syntaxes and used for analyses. Syntaxes allow up to 2 missing scores for variables with 6 items, and 1 missing score for variables with fewer than 6 items (Weinman et al., 2000; Moss-Morris et al., 2002).

IPQ-R subscales demonstrated test–retest reliability over 3 weeks ($r=0.46$ to 0.88) and 6 months ($r=0.35$ to 0.82), with the greatest stability demonstrated for causal attributions and identity; however, data were limited to a small sample of 28 renal dialysis patients for the 3 week assessment and 75 individuals with rheumatoid arthritis for the 6 month assessment (Moss-Morris et al., 2002). Internal reliability (Cronbach’s $\alpha=0.75$) and discriminant validity between the scale reflecting somatisation (i.e., symptoms experienced since having the illness) and the scale reflecting beliefs about symptoms associated with the illness (paired samples t -test [15.94], $p<0.001$) was reported in 711 individuals representing eight different illnesses, including rheumatoid arthritis, type II diabetes mellitus, asthma, chronic and acute pain, multiple sclerosis, myocardial infarction and human immunodeficiency virus (Moss-Morris et al., 2002). Internal reliability was demonstrated for scales reflecting the seven illness perception constructs (Cronbach’s α ranging from 0.79 to 0.89) and four causal attributions (Cronbach’s $\alpha=0.67$ to 0.86 for scales with >2 items) (Moss-Morris et al., 2002). The IPQ-R

discriminated between individuals with acute (n=35) versus chronic (n=63) pain across each subscale.

Barrier self-efficacy

The Barrier Self-Efficacy Scale for Intermittent Claudication (BSES) is a 7-item disease-specific measure of individuals' confidence in their ability to engage in walking when faced with specific barriers, and was developed from elicitation interviews with eight individuals newly diagnosed with IC (Cunningham, 2010). Items are presented on 11-point Likert scales (0=not at all confident, 10=extremely confident) and follow a common stem, "How confident are you that you can do a walk of at least 30 minutes, at least 3 times a week, walking until the claudication is almost unbearable before resting", and include the following 7 scenarios: bad weather, walking uphill, walking alone, having a partner who walks quickly, walking up a flight of steps, feeling tired, having nowhere to stop and rest. Two items from the original scale, walking in good weather and on flat terrain, were omitted in the current research because they reflect facilitators, not barriers. Scores across the remaining 7 items were summed and the total used in analyses to reflect barrier self-efficacy, with higher scores reflecting more positive self-efficacy. The original 9-item scale demonstrated good internal consistency (Cronbach's $\alpha=0.97$), and distinguished adherers from non-adherers to walking recommendations in a sample of 71 individuals with established IC (OR 22.3, 95% CI 1.34, 369.50, $p=0.030$). These findings suggest that the barriers identified by eight individuals with recently diagnosed IC who took part in elicitation interviews were generalisable to a wider group of individuals with established IC. Also, items are consistent with disease-specific barriers identified in focus groups of individuals with established IC (Galea et al., 2008).

Action planning

Action planning was assessed using a 4-item scale (Luszczynska and Schwarzer, 2003; Sniehotta et al., 2005a). In order to ensure relevance and specificity to walking, items on the original scale reflecting "exercise" were modified to "walking exercise". Four items assessed the extent to which individuals made detailed plans regarding when, where, how, and how often to do

their walking exercise. Each item was measured on a 4-point Likert scale (1=not at all true to 4=exactly true). Scores across the 4 items were summed and the total score used to reflect action planning, with higher scores reflecting greater action planning. A principal components analysis demonstrated factor loading of the original four items ($r=0.78-0.85$) and conceptual distinction from items assessing behavioural intentions in 352 individuals with coronary artery disease (Sniehotta et al., 2005b), and internal reliability of the scale (Cronbach's $\alpha=0.95$).

Action control

Action control was assessed using a 6-item measure (Sniehotta et al., 2005a). The original scale was modified from "exercise" to "walking exercise". Two-items each reflected the following self-regulatory processes: self-monitoring (e.g., "I have constantly monitored myself to ensure I walked frequently enough"), awareness of standards (e.g., "I have always been aware of my agreed walking action plan"), and self-regulatory effort (e.g., "I tried my best to follow through with my walking action plan"), and were measured on a 4-point Likert scales (1=not at all true to 4=exactly true). Scores across the 6 items were summed and the total score used to reflect action control, with higher scores reflecting more positive action control. The 6-item scale demonstrated good internal reliability (Cronbach's $\alpha=0.91$), and factor loading of items reflecting each of the three self-regulatory processes: self-monitoring ($r=0.86$), awareness of standards ($r=0.77$), and self-regulatory effort ($r=0.88$) (Sniehotta et al., 2005a).

3.4.4 Descriptive clinical variables

Health-related quality of life

The Medical Outcomes Survey Short Form-12 version 2 (SF-12v2) measures health-related quality of life over a 4 week recall period. The SF-12v2 includes 12 items reflecting general health, physical functioning, physical role, emotional role, bodily pain, vitality, mental health, and social functioning. Quality Metric Health Outcomes Scoring Software (version 4.5; OPTUMInsight, Lincoln, RI, USA) was used to compute Physical Component Summary (PCS) and Mental Component Summary (MCS) scores based on weightings for each item. Scores range from 0 to 100, with higher scores reflecting greater functioning. Scores are scaled to the mean

\pm SD 2009 United States adult population normal score of 50 ± 10 which is equivalent to the population normal score derived among a UK sample (Gandek et al., 1998). PCS and MCS scores demonstrated good test–retest reliability over 2 weeks ($r=0.89$ and 0.76 , respectively), and known group discriminant validity between individuals with a mental or physical condition ranging in severity (Ware et al., 1996). The SF-12v2 was evaluated in the Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) trial (Murphy et al., 2011), which compared 26 week supervised exercise therapy to angioplasty or optimal medical management alone for IC. The PCS, but not the MCS, was sensitive to change from baseline (MD 5.9 ± 10.1 , $p=0.047$ versus usual care) following supervised exercise therapy (Murphy et al., 2011).

Lower-limb symptom classification

The San Diego Claudication Questionnaire (SDCQ) is a disease-specific measure used to categorise PAD symptoms and distinguishes classic IC and atypical IC (McDermott et al., 1999; Criqui et al., 1996). The standardised 8-item survey is administered by a researcher, and used to define symptoms as 1) asymptomatic, defined as having no symptoms upon exertion or rest; or as having 2) atypical exertional leg symptoms, defined as symptoms that occur upon exertion and that do not meet the criteria for IC; 3) IC, defined as exertional calf pain that requires the individual to stop walking, resolves within 10 minutes of rest, and which does not begin at rest or resolve during walking; or 4) leg pain on exertion and rest. A categorical score from 1–4 was used to reflect symptoms. Sensitivity of the SDCQ compared with resting and post-exercise ABPI or history of revascularisation ranged from 69.9% to 96.1%; specificity for detecting PAD ranged from 46.5% to 81.8% compared with ABPI, history of revascularisation, or post-tibial and tibial-peroneal blood pressures (Schorr and Treat-Jacobson, 2013).

Perceived activity intensity

The Borg (1998) Rating of Perceived Exertion (RPE) assessed perceived activity intensity. Participants were asked to rate their perceived activity intensity before and after the 6MWT on a categorical scale ranging from 6=“no exertion at all” to 20=“maximal exertion”. In a meta-analysis of 437 studies evaluating the criterion validity of the RPE in healthy adults against

common physiological markers of activity intensity, mean sample-size-weighted coefficients ranged from $r=0.61$ (against ventilation as the criterion) to $r=0.72$ (against respiration rate as the criterion) (Chen et al., 2002). Borg RPE scores of 13–16 were correspondent with exercise training at 80–90% of maximal ventilator oxygen uptake in individuals with IC (Zwierska et al., 2005), consistent with ratings of moderate to vigorous activity in healthy older adults (Panton et al., 1996) and individuals with cardiovascular disease (Whaley et al., 1997).

Perceived pain intensity

The Borg (1998) Category–Ratio 10 Scale for Pain (CR10) assesses perceived pain intensity before and after the 6MWT. Participants were asked to rate the intensity of pain or discomfort in their legs before and after the 6MWT on a scale from 0=“nothing at all” to 10=“maximal”. The CR10 demonstrated large associations with RPE ($r=0.91$), heart rate ($r=0.82$), and blood lactate ($r=0.76$) among healthy male participants during a progressive cycle ergometry test (Borg et al., 1985). Among individuals with IC, the scale demonstrated good internal consistency (Cronbach’s $\alpha=0.88$) over four administrations repeated weekly (Galea and Bray, 2006). CR10 score corresponded with MWA during a shuttle walk test and was sensitive to change from baseline in 71 individuals with IC who underwent 24 weeks of supervised exercise therapy (Zwierska et al., 2005). The CR10 distinguished IC during peak exercise tolerance achieved by lower-limb ergometry (mean 6.8, 95% CI 6.3, 7.3) versus upper-limb ergometry (mean 4.5, 95% CI 3.8, 5.2; $p<0.001$), controlling for perceived exertion and blood lactate between groups (Zwierska et al., 2006).

Body mass index

BMI (kg/m^2) was obtained from height and weight estimates (fully clothed and wearing shoes) using standard scales.

3.5 Discussion

This research employs a mixed-methods approach, combining qualitative and quantitative evidence to inform the development and evaluation of a behaviour-change intervention targeting walking for IC. The TPB and CSM provide a theoretical underpinning for the thesis;

therefore, the Framework Method was applied, which is a qualitative approach that acknowledges existing theory and enables the exploration of theorised concepts (e.g., CSM and TPB constructs) alongside novel themes.

Qualitative evidence is considered alongside quantitative data derived from measures pertinent to this thesis and which include: walking, psychosocial constructs, and descriptive clinical variables. Walking, the primary outcome of this research, includes self-reported and objective measures of walking behaviour and ability. Self-reported measures of walking behaviour are easily implemented, and correspond with self-reported measures of theory-based cognitions, but can be subject to recall and social desirability bias (Ainsworth et al., 2012) and may lead to inflated covariances between constructs, compromising the generalisability and validity of findings (Kaiser et al., 2007; Podsakoff et al., 2003). In addition, few questionnaires assess walking exclusively, and those evaluated in general populations might not be appropriate or sensitive among people with IC (Gardner and Poehlman, 1998). Therefore, validated objective measures including a 6MWT and pedometer provided the primary outcomes reflecting objective walking ability and behaviour, respectively.

The 6MWT is a standardised assessment frequently used in research and clinical practice among people with long-term conditions, including IC, and is feasible to implement and acceptable to participants. Compared with treadmill assessments of walking ability, corridor-based measures, such as the 6MWD derived from the 6MWT, better reflect walking achieved in daily life (Nordanstig et al., 2014; McDermott et al., 2008), and are preferred by individuals with IC (Zwierska et al., 2004).

Test–retest reliability of the Omron Walking Style Pro pedometer and agreement against visual step count was demonstrated, and indicated that <3% of variance between pedometer and visual step count was due to random error. Most participants were male, and one participant was an outlier, who had a slow walking gait and high BMI, factors which could compromise the validity of pedometer data (Giannakidou et al., 2012; Schneider et al., 2003). However, data for

this participant were removed from analyses, and limits of agreement were acceptable suggesting the robustness of findings. Pedometers are widely used, acceptable to participants, and validated among older adults with long-term conditions, such as IC (Tudor-Locke et al., 2011).

ABPI readings were not obtained as standard practice at participating sites in this research, and were not available from medical records. Due to resource limitations, the ABPI was not assessed as an outcome of this research; therefore information on disease severity is limited to data on the location and extent of stenosis assessed by Duplex sonography, where available in participants' medical records.

Psychosocial constructs defined by the TPB and CSM were assessed by self-report, including a TPB questionnaire and the IPQ-R. To improve the saliency and resonance of the questionnaires, items were modified to reflect walking treatment and illness cognitions pertinent to IC, consistent with guidelines for developing the measures (Moss-Morris et al., 2002; Ajzen, 2002a). Adapted scales were also included assessing barrier self-efficacy for walking with IC, and constructs which have not previously been assessed in people with IC, including and action planning and action control, and therefore psychometric properties are not established in this population. However, validity and reliability of the scales were demonstrated in other populations with long-term conditions, including people with cardiovascular disease (Sniehotta et al., 2005b; Sniehotta et al., 2005a).

3.5.1 Conclusions

- A series of valid and reliable tests provide a balance of objective and self-reported measures, capturing the individual perspective on walking treatment and illness.
- Quantitative data considered alongside qualitative evidence provides rich evidence can be applied in the systematic development and evaluation of a complex intervention facilitating walking among people with IC.

Chapter 4. Do behaviour-change techniques increase walking in individuals with IC? A systematic review¹

4.1 Introduction

Walking is recommended as a first-line treatment strategy for individuals with IC. Yet there is a lack of available supervised centre-based programmes, and adherence to simple walking advice from a healthcare professional is low.

Walking uptake and adherence might be enhanced by theory-driven behaviour-change interventions (Chapter 2). Past reviews of structured home-based walking therapy do not identify or evaluate theory-based components of interventions (i.e., BCTs) that could facilitate walking uptake and adherence (Al-Jundi et al., 2013; Makris et al., 2012).

Systematic reviews identify and synthesise primary research, assess the quality of evidence, and evaluate consistency of findings across studies (Chalmers, 2005). This method underpins evidence-based medicine, guiding quality improvement while providing objective criteria to inform decision making about healthcare practice and policy (Davidson et al., 2003). Within the context of complex intervention development, such as walking programmes for people with IC, the MRC guidelines encourage a systematic review of the literature to identify the best available evidence underpinning a new intervention (Craig et al., 2008). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement provides a checklist for conducting and reporting systematic reviews of healthcare interventions, which aim to ensure consistent, transparent, and robust conclusions to be drawn (Moher et al., 2009).

However, systematic reviews of complex healthcare interventions, such as behaviour-change interventions for IC, present a number of methodological issues. Defining the intervention

¹ This review is published. Galea M, Weinman J, White C, et al. (2013) Do behaviour-change techniques contribute to the effectiveness of exercise therapy in patients with intermittent claudication? A systematic review. *Eur J Vasc Endovasc Surg* 46(1): 132-141.

under review, searching for and locating relevant evidence, standardising the selection of included studies, and synthesising the data are among these (Shepperd et al., 2009). A key element of the Consolidated Standards of Reporting Trials (CONSORT) statement on reporting complex healthcare interventions is the description of intervention components (Boutron et al., 2008; Shepperd et al., 2009). For behavioural interventions, recommendations include qualitative data on session content, delivery mode, supervision and materials, and quantitative data on the number and duration of sessions, and the Template for Intervention Description and Replication (TIDieR) checklist provides the minimum recommended data required for an intervention to be replicated (Hoffmann et al., 2014). Taxonomies of theory-based BCTs can be applied when reporting the content of complex interventions, in order to facilitate consistent, systematic, and explicit reporting of the active ingredients of complex theory-based interventions.

To date, evidence from interventions employing BCTs targeting walking among individuals with IC has not been synthesised and evaluated. If it is possible to identify techniques, or combinations of techniques, that have been successfully utilised to increase walking in people with IC, then these could be applied in addition to walking prescriptions (i.e., walking advice or supervised exercise therapy) in order to achieve greater outcomes.

4.1.1 Aims

This study aims to systematically identify and review the existing literature evaluating BCTs targeting walking in people with IC.

4.1.2 Objectives

This objectives of this study are:

- a) to identify and quantify BCTs that have been applied in walking interventions among people with IC;
- b) to evaluate whether BCTs improve MWA, PFWA, self-reported walking ability, and walking behaviour; and
- c) to determine whether specific BCTs are associated with improvements in outcomes.

4.2 Methods

4.2.1 Study design

A systematic review of RCTs was conducted.

4.2.2 Eligibility criteria

Studies met the following inclusion criteria:

- 1) RCTs including individuals with IC;
- 2) a group which received an intervention incorporating at least one BCT, as defined by Michie et al. (2011a), that explicitly targeted walking;
- 3) a group which received usual care (walking advice alone and/or optimised medical management) or an attention-control, but no administration of BCTs; and
- 4) MWA, PFWA, self-reported walking ability, or walking behaviour reported at least 3 months following intervention initiation.

Exclusion criteria were:

- 1) non-RCT designs;
- 2) studies including participants without IC;
- 3) active control or comparison groups (e.g., supervised or home-based exercise therapy);
- 4) publications in languages other than English.

4.2.3 Outcome variables

All outcome variables were evaluated at least 3 months following treatment initiation, with the longest follow-up assessment reported (Table 4.1). The primary outcome was MWA assessed by a standardised treadmill or corridor walk test. Secondary outcomes included PFWA, self-reported walking ability, and walking behaviour.

Table 4.1 Outcomes evaluated in a systematic review of behaviour-change interventions targeting walking among people with IC

Outcome	Measure
Primary outcome	
Maximal walking ability (MWA)	Standardised treadmill or corridor walk test
Secondary outcomes	
Pain free walking ability (PFWA)	Standardised treadmill or corridor walk test
Self-reported walking ability	Walking Impairment Questionnaire (WIQ) or other validated measure
Walking behaviour	Self-report or activity monitor

4.2.4 Data sources and search strategies

An electronic database search (Appendix 3) was conducted using Medline, PsychINFO, Embase, CINAHL, and Web of Science and by cross-checking reference lists of retrieved full-text articles. The OpenSINGLE database was searched for any appropriate grey literature and the active register of the *metaRegister* of Controlled Trials was searched for in-progress and unpublished trials. No language restrictions were imposed and databases were searched from their earliest records to December 2012. Search results were downloaded into bibliographic software (EndNote X6; Thompson Reuters, New York, NY, USA).

Search terms included MeSH, keyword, and wild-card terms located in the title or abstract for three broad concepts reflecting the disease (e.g., “intermittent claudication”, “peripheral arterial disease”), psychological interventions or variables (e.g., “behaviour modification”, “motivation”, “intervention”) and outcome (e.g., “walking”, “exercise”).

4.2.5 Study selection

Titles and abstracts of records were screened for eligibility, and the full texts of retained articles reviewed by two investigators (MGH and LMB) independently using a screening tool that was designed and piloted *a priori* (Appendix 3). Disagreement between reviewers was discussed until agreement was reached.

4.2.6 Data collection and computation

A data extraction tool was developed based on a template from the Cochrane Peripheral Vascular Diseases Review Group. This was pilot-tested on a selection of studies and refined. Data were collected on methods, study design, participants, intervention components, and outcome variables. At least two of four reviewers (MGH, CW [Academic Physiotherapist], LMB and SJB [Health Psychologist]) extracted data from all included studies. Disagreement was resolved by discussion.

MD scores and 95% CIs were calculated for data on MWA, PFWA, and walking behaviour, where possible, using Review Manager version 5.0 (RevMan 5.0; The Cochrane Collaboration, Copenhagen, Denmark). If available data were insufficient to calculate MDs, percentage change scores were calculated. Scores for self-reported walking ability were converted from ratio or percentage values to reflect a range from 0–100 on the WIQ (Regensteiner et al., 1990).

4.2.7 Evaluation of risk of bias and quality of evidence in individual studies

Study quality was evaluated using The Cochrane Collaboration (2011) Tool for Assessing Risk of Bias. Individual RCTs were rated as having high risk of bias (i.e., “low-quality” trials) or low to moderate risk of bias (i.e., “high-quality” trials) if there was evidence for the presence of ≥ 3 or < 3 sources of bias, respectively. In addition, RCTs were appraised using a 27-item checklist (Downs and Black, 1998; Deeks et al., 2003), which provided a broader evaluation of study quality, including reporting, internal and external validity, and power. The scale provides a Quality Index, ranging from 0–31, with higher scores reflecting lower risk of bias. The cumulative level of evidence from multiple studies, defined as “strong”, “moderate”, “limited”, “conflicting”, or “none”, was determined for each outcome variable in accordance with recommendations by van Tulder et al. (2003).

4.3 Results

4.3.1 Study selection

Six studies were identified for inclusion in the review (Collins et al., 2011; Cheetham et al., 2004; Gardner et al., 2011; Christman, 2003; Cunningham et al., 2012; Quirk et al., 2012). The initial database search resulted in 3575 identified records. After duplicates were removed, 2328 records remained, of which 2200 studies were excluded based on the content of their titles and abstracts. Full texts of the remaining 128 articles were reviewed, of which a further 122 articles were excluded (Figure 4.1).

Due to the heterogeneity of behaviour-change interventions, exercise prescriptions and outcome measures used, a narrative synthesis of the six included studies was conducted without meta-analysis.

4.3.2 Characteristics of included studies

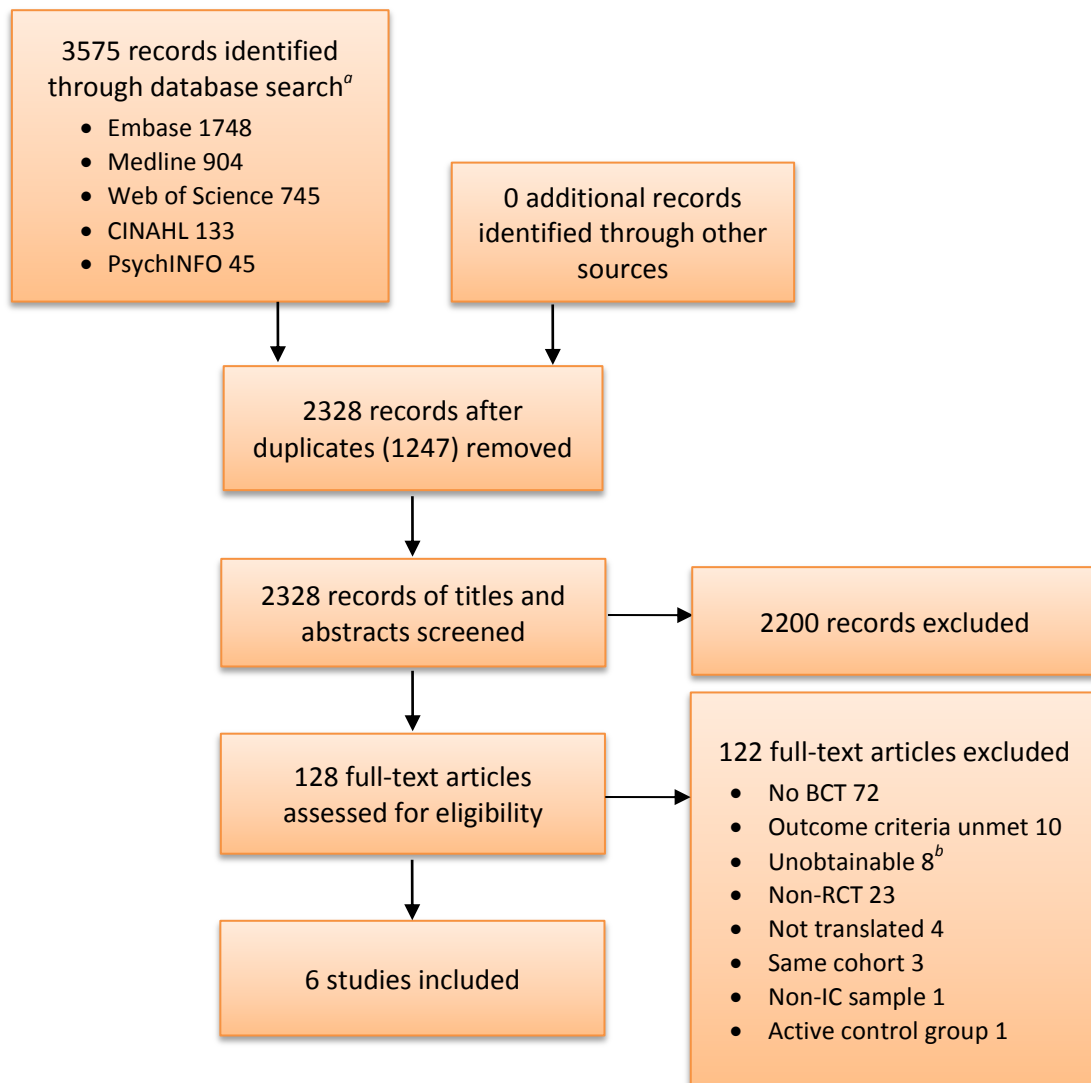
Study design and participants

Six RCTs evaluating BCTs to increase walking in IC included a total of 461 participants (Table 4.2). Two RCTs were pilot studies (Cunningham et al., 2012; Quirk et al., 2012) and one was a PhD thesis (Christman, 2003). The number of participants ranged from 19 (Quirk et al., 2012) to 145 (Collins et al., 2011). Mean age was 67.3 years and 64% (n=274/430) were male, reflecting the age and gender distribution of IC in the general population (Diehm et al., 2004). Baseline clinical measures were similar between control and intervention groups in all included studies, with the exceptions that one study reported a significantly higher MWA (Christman, 2003) and one reported greater medication use for IC (Collins et al., 2011) among the control group participants.

Outcomes

Three studies evaluated walking ability (MWA or PFWA) by treadmill protocol using a graded progressive treadmill test (Gardner et al., 2011; Collins et al., 2011; Christman, 2003), and one used a constant load treadmill test (Cheetham et al., 2004). Two RCTs included data on self-reported walking ability using the WIQ (Collins et al., 2011; Gardner et al., 2011). Three studies reported walking behaviour, two which used step activity monitors (i.e., accelerometers and pedometers) (Gardner et al., 2011; Cunningham et al., 2012), and one which used a standard questionnaire (IPAQ) to assess self-reported walking behaviour (Table 4.2).

Figure 4.1 Flow diagram illustrating the process of study selection for inclusion in a systematic review evaluating behaviour-change techniques to increase walking in people with IC



^aNo records were identified from the OpenSINGLE database or *metaRegister* of Controlled Trials. ^bUnavailable through a national library catalogue. BCT, behaviour-change technique; IC, intermittent claudication; RCT, randomised controlled trial.

Intervention compositions and settings

BCTs were administered in conjunction with walking advice in four studies (Quirk et al., 2012; Christman, 2003; Cunningham et al., 2012; Gardner et al., 2011) and with walking advice plus supervised exercise therapy in two studies (Cheetham et al., 2004; Collins et al., 2011). Interventions ranged in the number of BCTs applied from one (Cheetham et al., 2004; Quirk et al., 2012) up to seven (Collins et al., 2011). Two interventions were delivered through group sessions administered by a researcher or under medical or physiotherapist supervision (Cheetham et al., 2004; Christman, 2003) and four during individual consultation with a

researcher or exercise physiologist (Gardner et al., 2011; Collins et al., 2011; Cunningham et al., 2012; Quirk et al., 2012). Among the interventions delivered on an individual basis, two were delivered at a research centre or hospital (Quirk et al., 2012; Gardner et al., 2011), one included a baseline consultation plus telephone follow-up (Collins et al., 2011), and one was delivered in participants' homes (Cunningham et al., 2012).

Identified behaviour-change techniques

Overall, 11 BCTs (Michie et al., 2011a) were identified in the included studies (Table 4.3). The most frequent techniques reported were prompting self-monitoring of behaviour (n=3) (Christman, 2003; Gardner et al., 2011; Collins et al., 2011), feedback on performance (n=3) (Gardner et al., 2011; Christman, 2003; Collins et al., 2011), and barrier identification and problem solving (n=3) (Christman, 2003; Collins et al., 2011; Cunningham et al., 2012). Other BCTs included motivational interviewing (n=2) (Quirk et al., 2012; Cunningham et al., 2012), providing follow-up prompts (n=2) (Christman, 2003; Collins et al., 2011), information on the consequences of the behaviour in general (n=2) (Cunningham et al., 2012; Cheetham et al., 2004), behavioural goal setting (n=2) (Cunningham et al., 2012; Collins et al., 2011), and planning social support (n=2) (Collins et al., 2011; Christman, 2003). Action planning (Cunningham et al., 2012), use of a behavioural contract (Christman, 2003), and prompting practise of the behaviour (Collins et al., 2011) were each reported once.

Control groups

Control groups received walking advice in four studies (Gardner et al., 2011; Christman, 2003; Cheetham et al., 2004; Quirk et al., 2012), and walking advice or usual care plus an attention-control in two studies (Cunningham et al., 2012; Collins et al., 2011). One study (Gardner et al., 2011) was a three-arm trial comparing home-based exercise therapy with supervised exercise therapy or walking advice; for the purposes of this review, results are reported of comparisons between home-based exercise therapy and walking advice only, as the home-based exercise therapy group were engaged in self-monitoring and received feedback on performance as BCTs, as per the inclusion criteria.

Table 4.2 Characteristics of randomised controlled trials (RCTs) included in a systematic review of behaviour-change interventions targeting walking among people with IC

First author	Participants (n=461)	Exercise intervention	BCTs used	BCT delivery	Control	Outcome measure
Cunningham (2012)	n=58 (67% M), mean 65.3 years, 36% current smokers, mean ABPI 0.70, early IC.	Walking advice +BCT.	Information on consequences of walking exercise, behavioural goal setting, action planning, barrier identification/problem solving, motivational interviewing.	Individual consultation with a researcher (trainee health psychologist; 2× 1 hour, 1 week apart) delivered at home.	Walking advice plus attention-control.	WB (step activity monitor) at 4 months.
Gardner (2011) ^a	n=119 (48% M), mean 65 years, 10% current smokers, mean ABPI 0.73, established IC.	Walking advice +BCT.	Self-monitoring, performance feedback.	Individual consultation with an exercise physiologist (7× 15 minutes, 2×/month).	Walking advice.	MWA and PFWA (graded progressive treadmill test) ^b , SRWA and WB (step activity monitor) at 3 months.
Cheetham (2004)	n=59 (73% M), mean 67 years, 100% current or ex-smokers, mean ABPI 0.69, established IC.	Walking advice and SET (1× 30 minutes/week for 6 months) +BCT.	Information on consequences of walking exercise.	Motivation class (1× 5–10 minutes/week for 6 months) delivered under medical or physiotherapist supervision in conjunction with SET.	Walking advice.	MWA (constant-load treadmill test) ^c up to 12 months.

Christman (2003)	n=30 (55% M), mean 66.9 years, 47% current smokers, mean ABPI 0.61, established IC.	Walking advice +BCT.	Barrier identification/problem solving, self-monitoring, performance feedback, behavioural contract, follow-up prompts, planning social support.	Small group counselling delivered by a researcher (1× 1 hour/week for 12 weeks).	Walking advice.	MWA and PFWA (graded progressive treadmill test) ^d up to 6 months.
Collins (2011)	n=145 (69% M), mean 66.5 years, 14% current smokers, mean ABPI 0.95, DM and established IC.	Walking advice and SET (1× 50 minutes/week for 6 months) +BCT.	Behavioural goal setting, barrier identification/problem solving, self-monitoring, performance feedback, prompt practise of walking, follow-up prompts, planning social support.	Individual consultation (1× at baseline), practice exercise sessions (2× 1 hour), follow-up telephone consultation (1× biweekly for 6 months) delivered by a research coordinator and exercise instructor.	Usual care plus attention-placebo.	MWA (graded progressive treadmill test) ^b and SRWA at 6 months.
Quirk (2012)	n=19 (74% M), mean 73.2 years, 32% current smokers, mean ABPI not reported, established IC.	Walking advice +BCT. ^e	Motivational interviewing.	Individual consultation (up to 4× 1 hour).	Walking advice. ^e	WB (self-report) at 3 months. ^f

^aThis was a three-arm trial and included a group receiving supervised exercise therapy (SET) for which data are not presented. ^bGardner–Skinner treadmill protocol (Gardner et al., 1991): 3.2 kilometres/hour (2.0 miles/hour) constant speed, baseline 0% grade, increasing 2% every 2 minutes up to 14% at 16 minutes; maximum distance 0.8 kilometres (0.5 miles). ^c3.0 kilometres/hour at a 12% grade up to 15 minutes (Heidrich et al., 1995). ^dBaseline 1.6 kilometres/hour (1.0 miles/hour) and 5% grade, increasing in 5 minute intervals to 4.0 kilometres/hour (2.5 miles/hour) and 10% grade. ^eConfirmed by personal communication with author. ^fInternational Physical Activity Questionnaire, short form. ABPI, ankle–brachial pressure index; BCT, behaviour-change technique; DM, diabetes mellitus; IC, intermittent claudication; M, male; MWA, maximal walking ability; PAD, peripheral arterial disease; PFWA, pain-free walking ability; SDCQ, San Diego Claudication Questionnaire; SRWA, self-reported walking ability (assessed by the Walking Impairment Questionnaire); WB, walking behaviour.

4.3.3 Risk of bias and quality of evidence in individual studies

The mean (range) Quality Index (Downs and Black, 1998) was 20 (12–26). Possible bias occurred in several studies because of inadequate allocation concealment (Cheetham et al., 2004; Quirk et al., 2012; Christman, 2003; Collins et al., 2011) and none of the included studies blinded outcome assessment (Table 4.4).

Table 4.3 Summary of behaviour-change techniques identified in a systematic review of behaviour-change interventions targeting walking among people with IC

Behaviour-change technique	Definition ^a
Prompt self-monitoring of behaviour	Individual is asked to keep a record (e.g., diary) of behaviour as a method of changing behaviour (excludes outcome measures used for research)
Provide feedback on performance	Individual is provided data about their own recorded behaviour or receives comments on their behavioural performance
Barrier identification / problem solving	Individual is prompted to think about potential barriers (e.g., behavioural, cognitive, emotional, environmental, social and/or physical) and identify ways of overcoming them
Use of follow-up prompts	Intervention components are gradually reduced in intensity, duration and/or frequency over time (e.g., letters or telephone calls are used instead of face-to-face consultations)
Provide information on consequences of the behaviour in general	Information about the relationship between the behaviour and its possible or likely consequences, which are not individually personalised (e.g., usually based on epidemiological data)
Goal setting (behaviour)	Individual is encouraged to make a behavioural resolution (i.e., to decide to change or maintain change)
Plan social support / social change	Individual is prompted to plan how to elicit social support to achieve their target behaviour or outcome (e.g., support from family, friends, or healthcare professionals)
Action planning	Involves detailed planning of what the person will do, including when or how frequently, in which situation and/or where to engage in behaviour
Motivational interviewing	A clinical method including specific techniques that prompt the individual to engage in change talk in order to minimise resistance and resolve ambivalence to change
Agree behavioural contract	A written agreement on the performance of a specified behaviour, including a record of the resolution that is witnessed by another
Prompt practise	Individual is prompted to rehearse and repeat the behaviour, parts of the behaviour, or preparatory behaviours numerous times (e.g., building habits or routines)

^aDefinitions are according to the taxonomy of behaviour-change techniques defined by Michie et al. (2011a)

Table 4.4 Risk of bias in RCTs included in a systematic review of behaviour-change interventions targeting walking among people with IC

First author	Source of bias ^a							Quality Index ^c
	Random sequence generation	Allocation concealment	Participant and personnel blinding	Blinded outcome assessment	Incomplete outcome data	Selective reporting	Summary risk of bias ^b	
Cheetham (2004)	Yes	Yes	Yes	Yes	No	No	High	21
Christman (2003)	Yes	Yes	Yes	Yes	No	No	High	15
Collins (2011)	No	Yes	Yes	Yes	No	Yes	High	23
Cunningham (2012)	No	Yes	No	Yes	No	No	Low	24
Gardner (2011)	No	No	Yes	Yes	No	No	Low	26
Quirk (2012)	No	Yes	Yes	Yes	Yes	No	High	12

The presence or potential presence of a source of bias is indicated as “yes”. ^aSummary risk of bias was determined using The Cochrane Collaboration (2011) tool for assessing risk of bias. ^bStudies were rated as having high risk of bias (i.e., “low-quality” trials) or low to moderate risk of bias (i.e., “high-quality” trials) if there was evidence for the presence of ≥ 3 or < 3 sources of bias, respectively. ^cQuality Index scores range from 0–31, with higher scores indicating higher study quality and a lower risk of bias (Downs and Black, 1998).

4.3.4 Effects of behaviour-change interventions

MWA at least 3 months following treatment initiation

Four studies reported data on MWA (Table 4.5 and Appendix 3) (Gardner et al., 2011; Cheetham et al., 2004; Christman, 2003; Collins et al., 2011). One high-quality trial reported significantly greater improvements in MWA at 3 months in the intervention versus control groups (MD Δ 134.0 seconds, 95% CI 39.7, 228.3; $p=0.005$) (Gardner et al., 2011). That study compared an intervention providing BCTs plus walking advice with walking advice alone. Among low-quality trials, one study reported improvements in 3 month MWA following BCTs plus walking advice and weekly supervised exercise therapy versus walking advice alone (median Δ 130% versus control 70%; $p<0.001$) (Cheetham et al., 2004). Two low-quality RCTs demonstrated no benefit of intervention versus control on MWA. One showed no difference 3 months following BCTs plus walking advice compared with walking advice alone (MD -3.9 minutes, 95% CI -8.2, 1.1; $p=0.13$) (Christman, 2003) and one showed no difference at 6 months following BCTs plus walking advice and weekly supervised exercise therapy versus a non-exercise attention-control group (MD 14.7 metres, 95% CI -69.0, 39.6; $p=0.60$) (Collins et al., 2011).

PFWA at least 3 months following treatment initiation

Three studies reported data on PFWA (Table 4.5 and Appendix 3). One high-quality trial (Gardner et al., 2011) reported greater improvements in PFWA at 3 months following BCTs plus walking advice compared with walking advice alone (MD Δ 150.0 seconds, 95% CI 65.5, 234.5; $p=0.0005$). Among low-quality trials, there was no difference in PFWA at 3 months following BCTs plus walking advice compared with walking advice alone (MD -2.0 minutes, 95% CI -5.7, 1.7; $p=0.29$) (Christman, 2003) or at 6 months following BCTs plus walking advice and weekly supervised exercise therapy versus an attention-control group (MD 14.4 metres, 95% CI -47.5, 76.3; $p=0.65$) (Collins et al., 2011).

Self-reported walking ability at least 3 months following treatment initiation

Data on self-reported walking ability were available from two studies (Table 4.5 and Appendix

3). One high-quality trial found no difference at 3 months in self-reported walking ability following BCTs plus walking advice (mean \pm SD Δ for distance 10.0 \pm 25.0 and speed 11.0 \pm 22.0) versus walking advice alone (mean \pm SD Δ for distance 1.0 \pm 34.0 and speed 4.0 \pm 25.0; both p =NS) (Gardner et al., 2011). One low-quality trial reported mixed findings. There was a greater improvement in self-reported walk speed (mean \pm SE Δ 5.7 \pm 2.2 versus control 1.9 \pm 2.8; p =0.034), but not walking distance (mean \pm SE Δ 5.6 \pm 3.5 versus control 1.4 \pm 3.3; p =0.383) following BCTs plus walking advice and weekly supervised exercise therapy versus an attention-control (Collins et al., 2011).

Walking behaviour at least 3 months following treatment initiation

Data on walking behaviour were available from three studies, including two high-quality trials (Table 4.5 and Appendix 3). In one high-quality study, change in mean 6 day step count was greater following BCTs plus walking advice versus an attention-control plus walking advice (MD 1674.2 steps, 95% CI 156.0, 3188.4; p =0.03) (Cunningham et al., 2012). In a second high-quality study, there was no difference in mean 7 day activity time following BCTs plus walking advice versus walking advice alone (MD -1 minutes/day, 95% CI -41.1, 39.1; p =0.96) (Gardner et al., 2011). In a low-quality pilot RCT, BCTs did not affect self-reported walking behaviour (Quirk et al., 2012).

Table 4.5 Data extracted from studies included in a systematic review of behaviour-change interventions targeting walking among people with IC reflecting effects on MWA, PFWA, self-reported walking ability, and walking behaviour

First author	Outcome				
	Maximal Walking Ability	Pain-Free Walking Ability	Self-reported walking ability		Walking behaviour
			Distance	Speed	
Cunningham (2012)	–	–	–	–	Greater change (1358 steps) versus control (-227 steps) at follow-up; p<0.001
Gardner (2011) ^a	Greater change in walking time (124 seconds ±193) versus control (-10 seconds ±176); p<0.05	Greater change in walking time (134 seconds ±197) versus control (-16 seconds ±125); p<0.05	p=NS	p=NS	p=NS
Cheetham (2004)	Greater walking distance (median 304 metres) versus control (median 175 metres); p<0.001	–	–	–	–
Christman (2003)	p=NS	p=NS	–	–	–
Collins (2011)	p=NS	p=NS	p=NS	Greater change (5.7 ±18.7) versus control (-1.9 ±23.9); p=0.034. ^b	–
Quirk (2012)	–	–	–	–	p=NS

Data are presented as intervention versus control and represent mean ±standard deviation (SD) unless indicated otherwise. ^aThis was a three-arm trial and included a group receiving supervised exercise therapy for which data are not presented. ^bSD derived from data published as standard error. NS, non-significant.

4.4 Discussion

This systematic review is the first evaluation of BCTs alongside exercise for improving walking in individuals with IC. The existing evidence is limited to a small number of mostly low-quality trials using 11 BCTs, and there is insufficient evidence to draw conclusions on the effectiveness of these strategies for improving MWA. Given that access to supervised centre-based exercise therapy and adherence to walking advice is limited among individuals with IC (Bartelink et al., 2004; Makris et al., 2012), this is an important finding as it highlights the need for more rigorous trials of behaviour-change interventions for this population.

While data from two high-quality trials demonstrate that BCTs supplementary to exercise prescription improved MWA and PFWA (Gardner et al., 2011) and increased walking behaviour (Cunningham et al., 2012), further evidence from four low-quality trials was conflicting. The high-quality trials were more recent publications, and may reflect improvements in study design and reporting, and a growing recognition of the need to explicitly support behaviour-change among individuals with IC. However, findings of both trials were at risk of bias due to lack of blinding of the outcome assessor, which may be important given that walk test performance could be influenced by interaction with personnel.

While RCTs are considered the gold standard for synthesising the existing evidence, poor design and reporting can introduce bias and reduce the robustness of data (Black, 1996; Kunz and Oxman, 1998). In addition, RCTs often lack ecological validity, limiting the implementation of findings to practice. For example, three of the included studies reported intervention delivery by a researcher, and further evaluation of training and delivery by a suitable healthcare professional, such as a physiotherapist, would be required prior to implementation.

In the current review, 11 BCTs were applied to increase walking in individuals with IC. These included self-monitoring, providing feedback on walking performance, and barrier identification with problem solving. These techniques are useful for increasing an individual's confidence in their ability to walk and can be easily incorporated into clinical practice by

healthcare professionals when prescribing home-based walking among people with IC. However, there were 29 additional theory-based techniques in the applied taxonomy (Michie et al., 2011a) and, following the latest update to the taxonomy to include 93 items, many more techniques that have not been applied to increase walking among individuals with IC, some which may warrant investigation.

Subsequent to this review, two trials have been reported on group-based behaviour-change interventions for people with IC. Structured EDucation for Rehabilitation in Intermittent Claudication (SEDRIC) is a pilot trial of a group-based intervention targeting self-directed walking (Tew et al., 2015). BCTs included goal setting, action planning, self-monitoring, feedback on performance, and prompted follow-up, delivered via one 3 hour workshop and a booster follow-up provided by telephone 2 weeks later. Data from 23 participants demonstrated significant improvements in objective walking ability (6MWD and treadmill-derived MWD, MD 44.9 metres [95% CI 6.9, 82.9] and 173 metres [95% CI 23, 322], respectively) and self-reported walking ability (WIQ speed, distance, and stair climbing MD 21.0 [95% CI 8.6, 35.0], 21.0 [95% CI 3.8, 38.1], and 30.7 [95% CI 6.4, 55.0], respectively), but not daily walking at 6 week follow-up (MD 400 steps/day [95% CI -827, 1708]). Treatment increased self-efficacy to walk and personal control, but not other illness perceptions assessed by the Brief Illness Perceptions Questionnaire (Broadbent et al., 2006). While these results are promising, this was a small study of mostly male participants, and so statistical comparisons must be interpreted with caution. In addition, only a short-term (6 week) follow-up is reported.

The Group-Oriented Arterial Leg Study (GOALS) (McDermott et al., 2012; McDermott et al., 2013b) is an RCT of group-mediated Cognitive Behaviour Therapy targeting barriers to self-directed walking in 194 individuals with IC. The intervention comprised a 6 month programme of weekly sessions lasting 90 minutes, including a 45 minute facilitator-led discussion and 45 minutes of track-based supervised exercise therapy. Reported BCTs included behavioural

goal setting, self-monitoring, feedback on performance, instruction on how to engage in walking, instruction on where and when to engage in walking, and general information on the consequences of the behaviour. Compared with an attention-control, the intervention increased 6MWD (MD 53.5 metres, 95% CI 33.2, 73.8), MWA, PFWA, accelerometer-based walking behaviour, and self-reported walking distance and speed (assessed by the WIQ); there were no differences in health-related quality of life. Participants in the intervention group also reported increased exercise self-efficacy and changes in cognitive-behavioural processes; however, changes were independent of improvements in 6MWD (Rejeski et al., 2014). Only a per-protocol analysis was reported and participants who did not attend a two-session run-in period were excluded (McDermott et al., 2012), so findings may be biased toward adherent and highly-motivated individuals. Additionally cost-effectiveness was not reported, and such a lengthy and intensive intervention might not be easily implemented or feasible in practice.

The SEDRIC and GOALS trials corroborate present findings supporting self-monitoring, feedback on performance, and barrier identification with problem solving for improving walking in IC, through interventions that explicitly address the challenge of exercise adherence. In the present review, four (Cunningham et al., 2012; Christman, 2003; Collins et al., 2011; Quirk et al., 2012) of the six included studies were designed with the objective of addressing the problem of exercise motivation among individuals with IC, by employing BCTs. However, only one of these studies (Cunningham et al., 2012) referred to a version of the Behaviour Change Taxonomy employed in the present review. The drive for standardised reporting of intervention components is relatively contemporary, and the inclusion of studies predating the Behaviour Change Taxonomy required a degree of interpretation by the reviewers. Moreover, BCTs that were not included in the version of the taxonomy applied may have been overlooked. Synthesis of data from recent and future studies that adhere to standardised reporting guidelines, including a more comprehensive taxonomy, should be less ambiguous.

Among the four studies which deliberately employed BCTs, only two were underpinned by a theoretical model: Cunningham et al. (2012) applied the CSM (Leventhal et al., 1980; Leventhal et al., 1984) and Christman (2003) applied the Transtheoretical Model, which describes behaviour-change as a progression across five stages including precontemplation, contemplation, preparation, action, and maintenance, and as susceptible to relapse (Prochaska and Diclemente, 1983). However, the 40 item Behaviour Change Taxonomy was not explicitly informed by either of these two theories, and BCTs identified within these two studies do not necessarily map onto the respective theories employed. This finding can be viewed as a limitation of the taxonomy itself, which is not exhaustive. While the taxonomy provides a useful methodological tool for specifying intervention content, the authors acknowledge that BCTs need to be better linked to theories of behaviour change (Michie et al., 2011a).

4.4.1 Methodological considerations

Statistical data synthesis could not be performed for this review because of a high degree of clinical and methodological heterogeneity, primarily due to variations in intervention protocol and setting between studies, and lack of control for these factors within studies. In addition, in two studies (Cheetham et al., 2004; Collins et al., 2011), where BCTs were provided alongside supervised exercise therapy, it is difficult to distinguish the effects of BCTs beyond the benefits of the exercise alone. However, both studies provided only one supervised exercise session per week, which is a suboptimal exercise dose that does not meet guidelines for supervised exercise therapy for individuals with IC (Norgren et al., 2007; Fakhry et al., 2012). Thus, it is possible that the change in walking ability is not solely attributable to supervised exercise therapy in these studies, and that BCTs targeting self-directed walking behaviour might influence outcomes. Data from the study by Gardner et al. (2011), which applied BCTs to increase self-directed walking, demonstrate that BCTs have the potential to increase participation such that individuals achieve gains in walking ability that are at least comparable to supervised exercise therapy.

BCTs are intended to target and modify known motivational factors, for example, a person's beliefs about walking and the outcome of performing it, or their ability to engage in walking treatment for IC. However, included studies did not evaluate treatment effects on the psychosocial constructs underpinning the BCTs implemented, so it was not possible to determine whether the intervention successfully altered psychosocial variables or if other factors influenced walking. Moreover, as most interventions combined multiple BCTs, the independent effects of each could not be determined.

This study demonstrates a need to tailor interventions to the population of individuals with IC, and, importantly, to the individual. Interventions that provide a fixed package in order to facilitate self-management through walking may not be suitable or effective, and could explain the lack of evidence for behaviour-change interventions increasing walking in people with IC.

4.4.2 Conclusions

- Eleven BCTs were identified in this review and, in particular, self-monitoring, feedback on performance, and barrier identification with problem solving, could be easily combined with exercise prescription and walking advice in clinical practice.
- There is limited evidence from one high-quality RCT supporting BCTs for increasing MWA and PFWA, and one high-quality RCT supporting BCTs for increasing walking behaviour among people with IC.
- Recent evidence indicates a growing body of research on theory-driven behaviour change interventions targeting walking for IC, which are group-mediated, and suggests a need for tailored, individual interventions.

Chapter 5. Individual experiences of and beliefs about walking for IC: a qualitative study

5.1 Introduction

While RCTs underpin evidence-based practice in healthcare research (Sibbald and Roland, 1998), inclusion of broader sources of evidence is endorsed to ensure the context, meaning, and purpose behind health behaviour are not overlooked (Snape and Spencer, 2003; Kelly et al., 2002). Qualitative health research enables an understanding of behaviour, cognitions, and interactions between phenomena to ensure culturally appropriate and tailored interventions (Pope and Mays, 1995), and can establish the need for treatment, define key constructs (Nastasi and Schensul, 2005), and identify the theoretical targets for an intervention (Craig et al., 2008).

Past qualitative research involving individuals with IC has largely sought to understand participants' lived experiences of the condition, and its impact on quality of life. Findings demonstrate broad implications of IC for psychosocial, emotional, and physical functioning (Wann-Hansson et al., 2005; Treat-Jacobson et al., 2002), but does not explicitly address the experience of walking with IC, or identify targets for intervention.

Three qualitative studies have explored walking among individuals with IC. Galea et al. (2008) reported barriers and facilitators to walking drawn from focus groups involving a sample of 15 people with IC. General (e.g., lack of time, feeling tired) and disease-specific (e.g., a need to take frequent rest breaks, companionship on walks, uneven walking terrain) factors were identified and reflected personal, environmental, and behaviour-related variables. While identifying and overcoming barriers to walking is an important behaviour-change strategy (Michie et al., 2011a), perceived barriers and facilitators to walking do not fully explain walking behaviour (Galea and Bray, 2007), and other factors should be explored which could contribute to behaviour change. In addition, most participants in that study had attended supervised centre-based exercise therapy, and individuals who receive walking advice or

home-based walking therapy might report different experiences and factors that influence walking.

Focus groups with 24 individuals with IC were conducted to inform the development of SEDRIC, a self-management programme targeting walking (Gorely et al., 2015). Uncertainty and lack of support or empathy were identified as themes illustrating the experience of living with IC. Examples of participants' uncertainty included the possibility of exacerbating symptoms by walking, their ability to do enough walking to make a difference, and the best dose of exercise for their condition. Benefits and barriers to physical activity, and a lack of motivation, were also described, and are consistent with previous research (Galea et al., 2008). Participants were mostly male, White, and had been treated conservatively, and may not reflect the wider population of people with IC, including those who had undergone revascularisation.

Another qualitative study included only individuals with IC who had undergone revascularisation (Cunningham et al., 2014). Participants avoided walking, viewed IC as acute and treatable, and reported a limited understanding of the cause and broader consequences of IC, suggesting illness beliefs are salient. The use of medical terminology was highlighted as a barrier when discussing their condition with a healthcare professional. This research was framed within the CSM, however *a priori* theory-based themes were not reported, which could bias results, and there was a lack of explanatory evidence linking illness and treatment beliefs with walking, so it is unclear which factors should be targeted in walking interventions for IC.

The objective of this study is to explore the experience of living with IC, and the role of illness and treatment beliefs in understanding walking, to inform the development of a home-based intervention to increase walking in IC. This study acknowledges the TPB and CSM as models for explaining walking among individuals with IC, and therefore employs the Framework Method to elicit and explore salient, theory-based constructs, while allowing new themes to emerge that support an understanding of walking with IC.

5.1.1 Aims

The aim of this study is to explore experiences of walking, and cognitions about walking treatment and illness, among people with IC, in order to understand and explain walking and to inform the development of an acceptable intervention to facilitate walking among individuals with IC.

5.1.2 Objectives

According to the Framework Method, the functions of qualitative research are contextual, explanatory and generative (Ritchie, 2003); therefore, the objectives of this study are:

- a) to describe and understand the experience of walking with IC (contextual);
- b) to identify and explain beliefs held by individuals with IC regarding their illness and walking (explanatory); and
- c) to develop an thematic map of walking behaviour among people with IC (generative).

5.2 Methods

5.2.1 Study design

A qualitative study using semi-structured in-depth individual interviews and applying the Framework Method was conducted.

5.2.2 Ethical approval

Ethical approval was obtained on 30 August 2011 from the National Research Ethics Service (NRES) Committee London – London Bridge (reference 11/LO/0871; Appendix 1) and approval from the Departments of Research and Development, Guy's & St Thomas' NHS Foundation Trust was confirmed on 12 September 2011 and from King's College Hospital NHS Foundation Trust on 31 January 2013 (CSP reference 73416).

5.2.3 Eligibility criteria

Participants met the following inclusion criteria:

- 1) adults aged ≥ 18 years; and
- 2) IC diagnosed by a vascular clinician, and based on results of established methods (e.g., ABPI, duplex ultrasound, computed tomography, magnetic resonance imaging) against recommended criteria (Norgren et al., 2007).

Reasons for exclusion were:

- 1) revascularisation (e.g., endovascular treatment or bypass surgery) scheduled in the upcoming 3 months;
- 2) the presence of a comorbidity other than IC (e.g., knee osteoarthritis, back pain) self-reported as the primary limitation of walking;
- 3) the presence of a condition for which it is inadvisable to increase walking (e.g., unstable angina); and/or
- 4) inability or refusal to provide informed consent.

5.2.4 Sampling and recruitment

A purposive sample of eligible participants was recruited from vascular outpatient clinics at Guy's & St Thomas' NHS Foundation Trust between 1 September 2011 and 31 May 2014. Sampling aimed to achieve a range of age, gender, and duration of symptoms (i.e., ≤ 2 years or >2 years). The initial target sample size was 12, and the stopping criterion was defined as no new information obtained from three consecutive interviews (Francis et al., 2009).

Medical records of attendance at an outpatient clinic for a scheduled appointment were screened and eligible individuals were identified and informed of the study by the direct healthcare team. If interested, potential participants were provided with verbal and written information about the study and met with the researcher (MGH) who answered any questions and obtained the participants' contact details. One week later, the potential participant was telephoned and invited to enrol onto the study. If they agreed to take part, then a letter was delivered to the participant's home address confirming details of the scheduled appointment and directions to the site. Participants received a reminder telephone call within 2 days of their scheduled appointment.

5.2.5 Outcome measures

Sociodemographic and clinical characteristics. Sociodemographic characteristics (age, gender, ethnicity, smoking status, comorbidities, duration of symptoms, and other mobility-limiting

conditions) were assessed by self-report (Appendix 4). Data on previous revascularisation were obtained from medical records.

Self-reported walking behaviour. The walking subscale of the Physical Activity Scale for the Elderly (PASE), a valid and reliable measure (Washburn et al., 1993; Dinger et al., 2004), was used to assess walking behaviour. Participants reported their average walking frequency (0 days=never, 1–2 days=seldom, 3–4 days=sometimes, or 5–7 days=often) and duration (less than 1 hour, 1 but less than 2 hours, 2–4 hours, or more than 4 hours) over the past 7 days (Appendix 4).

5.2.6 Topic guide development

A topic guide was developed which reflected the theory-based objectives of the study, and addressed cognitive processes related to illness and walking treatment for IC (Appendix 4). Advice on content and structure of the topic guide was provided from an experienced qualitative researcher (B Grunfeld, personal communication, 17 March 2011) in the Institute of Psychiatry, Psychology & Neuroscience, King's College London. The topic guide was pilot tested during a mock interview with a clinical researcher and refined iteratively after interviews with participants with IC (Table 5.1).

5.2.7 Procedure

A 75 minute appointment was arranged either at the participant's home or at King's College London (London, UK), depending on participant preference. Following informed consent, sociodemographic information and clinical characteristics were obtained by self-report, participants completed the PASE questionnaire, and the SDCQ was administered. Interviews followed the topic guide (Appendix 4) and were audio-recorded.

5.2.8 Analyses

Interviews were transcribed verbatim by one researcher (MGH) and analysed using NVivo 9 (QSR International Ltd, Southport, UK). Key stages of the Framework Method were applied, including transcription, familiarisation, coding, development, and application of the analytical framework, charting, and interpretation (Chapter 3) (Gale et al., 2013).

Table 5.1 Topic guide exploring illness and treatment experiences and beliefs among people with intermittent claudication

Introduction	Nature of project, confidentiality, duration of interview, any questions.
Opening question	How did you realise you had PAD? What has your experience been since your diagnosis?
Illness beliefs	Can you tell me about PAD?
	Can you describe your condition?
	<ul style="list-style-type: none"> • Complications? Symptoms??
	What is it like having PAD?
	<ul style="list-style-type: none"> • How do you feel having PAD?
	Tell me about your symptoms.
	<ul style="list-style-type: none"> • How do your symptoms affect you? • How do you address the pain? • What do you think it means?
	Is there anything that you can do about your PAD?
	Does your condition change over time?
	What caused your PAD?
Treatment beliefs	What can be done for your condition?
	Do you know very much about walking exercise?
	Could walking exercise affect your PAD? How?
	Have you tried walking or currently walk? What is it like?
	What do you think about walking as a way of treating PAD??
	Do other people feel you should be walking?
	<ul style="list-style-type: none"> • Are their opinions important to you?
	Do you know anyone else with PAD?
	How do you feel about starting/continuing walking?
	<ul style="list-style-type: none"> • Barriers? Facilitators?
Closing remarks	Any additional comments?

PAD, peripheral arterial disease.

5.3 Results

5.3.1 Participant characteristics

Nineteen participants (n=6 women; mean \pm SD age 66 \pm 9 years) were included. The study stopping criterion was not met by the initial target sample of 12, and a further 7 participants were recruited to attain data saturation. As the initial 12 participants identified themselves as White, individuals from ethnic minorities were purposively sampled among the 7 latter participants. More men than women were sampled, reflecting the higher prevalence of IC among men (Diehm et al., 2004). Over half (53%; n=10) had experienced IC for \geq 2 years and 16 (84%) participants reported walking on \geq 3 days/week (Table 5.2).

Table 5.2 Sociodemographic and clinical characteristics of participants in a qualitative study exploring individual experiences of and beliefs about walking with IC

Variable	Value, n (%)
Age, years	66 \pm 8.9 ^a
Male gender	13 (68)
Married	11 (58)
White ethnicity	17 (90)
Current smoker	7 (37)
Cardiovascular risk factors	
Diabetes mellitus	6 (32)
Cardiovascular disease	12 (63)
Renal disease	2 (11)
Heart attack	3 (16)
Stroke	2 (11)
Duration of symptoms $>$ 2 years	10 (53)
Past revascularisation	5 (26)
Past supervised exercise therapy	8 (42)
Walking frequency ^{bc}	
Never	0 (0)
Seldom (1–2 days)	1 (5)
Sometimes (3–4 days)	7 (37)
Often (5–7 days)	9 (47)
Walking duration ^b	
<1 hours	10 (53)
1–2 hours	5 (26)
2–4 hours	2 (11)
>4 hours	2 (11)

n=19. ^aData are mean \pm SD. ^bBased on the walking subscale of the Physical Activity Scale for the Elderly (Washburn et al., 1993). ^cData missing for 2 participants.

5.3.2 Descriptive and explanatory themes

Two superordinate themes were identified: 1. Walking is an overlooked self-management opportunity and 2. Tailored walking guidance is desired. Five subthemes further illustrate these findings (Table 5.3).

Table 5.3 Explanatory themes and subthemes emerging from qualitative interviews exploring individual experiences of and beliefs about walking with IC

Theme/subtheme	Summary
1. Walking is an overlooked self-management opportunity	Walking is not understood as treatment, or as a first-line management option. A medical model is the predominant approach to illness.
1.1 IC is benign and leg pain can be overcome	IC is an isolated, harmless symptom, not warranting surgery, and leading to varied beliefs about the necessity of walking treatment.
1.2 IC is severe and there is nothing I can do	A high impact of IC on lifestyle and work, leading to hopelessness, lack of control, and attempted coping strategies, although walking is overlooked.
2. Tailored walking guidance is desired	Lack of awareness of walking guidelines, and concern regarding necessary and appropriate self-management.
2.1 Varied outcome expectations of walking	Uncertainty about the realistic consequences of regular walking exercise, or mechanisms of benefits.
2.2 Barriers to walking to intensity	Uncertainty about walking through pain, inability to feel exhilarated by symptom-limited walking exercise.
2.3 Limited purposeful walking for exercise	Descriptions of incidental bouts of walking incorporated into daily life and activities, and not deliberately for achieving exercise.

n=19. IC, intermittent claudication.

Walking is an overlooked self-management opportunity

Most participants had discussed the role of walking with a healthcare professional but did not consider it a first-line treatment strategy for IC, or did not regard walking as a treatment for IC at all:

“There’s no treatment. I’m getting no treatment, not for this. I’m getting advice, and the advice is ‘try to walk through it’. That’s the only advice I’ve ever had.” (007A, male, 69 years)

Other participants believed that walking could slow the progression of their symptoms, or delay or replace higher-risk interventions, such as revascularisation:

“I’m hoping that I can stave off this operation because, from what I’ve heard, I don’t really want that. And hopefully I can improve my lifestyle by strengthening these vessels up and feeding my calf muscle more. I mean, I don’t know whether that’s possible.” (001A, male, 67 years)

Individuals who had undergone revascularisation, but still experienced IC, anticipated another bypass or angioplasty to alleviate their symptoms, not recognising walking as a treatment option. One participant, who was prepared to undergo a second revascularisation, was surprised when told instead to try walking:

“They told me, ‘We’re sending you home. We’re going to ask you to walk through the pain of claudication in your left calf’. I said, ‘You’re joking! You can’t walk with cramp!’ I was quite willing for them to do the operation ...and if they had done that straight away, I would have gone along with it.” (005A, male, 62 years)

The overlooked role of walking for IC is explained by two subthemes, which illustrate how treatment beliefs were framed around the perceived consequences of IC: 1.1 IC is benign and leg pain can be overcome; and 1.2 IC is severe and there is nothing I can do.

IC is benign and leg pain can be overcome

Most participants viewed their IC as benign and as having minimal impact on their day-to-day lives, and frequently did not recognise a need for walking or the potential for walking to improve their function.

Among these individuals, pain was not viewed as harmful, and IC was described as “a nuisance” (128B, female, 78 years) and something that “you just get on with” (001A, male, 67 years), or as an “inconvenience” (007A, male, 69 years). Leg pain was considered an isolated minor symptom:

“Ninety percent of the time I don’t even think of it because I’m not doing something that makes it hurt.” (010A, male, 64 years)

Despite the belief that IC was benign, some participants linked their condition with systemic comorbidities, and considered walking and other exercise as potentially useful for maintaining their general health. However, these beliefs were not consistently reflected in descriptions of walking behaviour. One individual expressed concern about systemic atherosclerosis, which hampered her walking efforts:

“I’m not thinking that my legs are going to cause me to collapse. I’m thinking, ‘because I have blockages in my legs, have I got blockages elsewhere, which could cause me to collapse?’” (002A, female, 79 years).

IC is severe and there is nothing I can do

Some participants viewed IC as severe and described a considerable impact on their lifestyle and work, and most did not describe regular walking or consider it a self-management

strategy. They expressed strong negative emotions, such as anger, frustration, humiliation and embarrassment, stress, fear, apathy, depression, and loneliness:

"I just get so frustrated, I cancelled plans. I was going to Germany to look at castles... I was going to go down the Rhine. But where's the castle? Oh, it's on top of the hill. And that means walking up hill, and that's a no-no." (003A, male, 52 years)

Functional limitations influenced participants' sense of identity. For example, some participants felt old because they linked walking impairment with ageing. Participants dissociated from the term "disease" and did not like to be perceived as "old" or "disabled" by their IC:

"If I was to say 'something disease', [my family] would think it is something serious, so I just don't say anything at all. I think they would start treating me as an old person, and I don't want to be treated as an old person." (012A, female, 68 years)

Participants who felt disabled by IC also described a lack of control over their condition and helplessness. They failed to recognise walking as a self-management opportunity, yet expressed concern about the possibility of a life- or limb-threatening treatment. Participants coped with IC by adapting their activities or planning ahead to minimise symptoms (e.g., choosing sedentary activities or hobbies).

One participant (005A, male, 62 years), with longstanding IC, described extensive coping strategies, including stress-avoidance, relaxation, following familiar walking routes, and goal setting. He was the only participant who reported a high impact of IC on his life, and described engaging in regular walking.

Tailored walking guidance is desired

All participants described engaging in walking; however, most were unaware of and did not achieve walking guidelines for IC (Norgren et al., 2007), regardless of the duration of their IC. The lack of guidance meant participants were uncertain about the appropriate walking dosage (both duration and intensity), and were worried about doing enough, as well as the possibility of “overdoing it” (005A, male, 62 years).

This conflict was partially alleviated in participants who had completed a supervised centre-based exercise programme, which provided structure and reassurance that they were exercising safely and effectively. In addition, these participants increased their understanding of IC, enabling them to cope with and manage their condition:

“I’m not mystified any more, about what can happen and all that, and I’ve come to accept that and I’m very grateful. The understanding of why I have peripheral [arterial] disease, what causes it – it means that when it comes on, I’m not confused or baffled or muddled.”

(025B, male, 73 years)

However, attending supervised exercise therapy did not facilitate independent walking, and participants described barriers such as comorbidities, leg pain, lack of motivation, and time. Overall, participants wanted definitive tailored guidance and support to achieve the walking recommendations:

“If there was an exercise programme that could help people like me, I think that would be fantastic. Even if it were only one we had to do on our own at home, but knowing we were doing the right things at the right time at the right pace and frequency, I think, would be extremely motivational.” (008A, female, 44 years)

This is further explained by three subthemes, which describe the consequences of a lack of tailored walking guidance: 2.1 Varied outcome expectations of walking; 2.2 Barriers to walking to intensity; and 2.3 Limited purposeful walking for exercise.

Varied outcome expectations of walking

A lack of clear instructions meant participants held mixed beliefs about the possible outcomes of walking for IC. Those who recognised the potential for walking to improve or stabilise their condition did not necessarily report engaging in the recommended walking.

Some participants understood that walking was superior to other forms of exercise for IC, believing that walking would “open vessels”, whereas gardening “burns calories” (128B, female, 78 years). In some instances, there was a sense that walking was helpful, despite confusion about the cause of IC:

“I think being on my feet is a help, because I think the more I walk the blood is flowing... I don’t understand the pain, but maybe it’s not flowing as it should when I’m walking. I don’t know.” (012A, female, 68 years)

Other participants believed walking is good for their general health, and not harmful but were sceptical about walking to improve their IC:

“I think walking helps generally, actually. Whether it could specifically help my condition now, I don’t know. But I think that if you can walk and the more you walk you’re better all around.” (002A, female, 79 years).

Some individuals had attempted walking but either found no improvement or were perplexed by the notion that walking would get easier despite the pain, suggesting that advice to walk was counterintuitive:

“Well, the more I walk, the more pain I get. It doesn’t get any easier by walking. What you’re implying is that if I walk more, then my condition will ease. It won’t. I’ve proved this out.” (007A, male, 69 years)

Barriers to walking to intensity

A lack of tailored guidance, and specifically instructions on “walking through pain”, led to uncertainty about the appropriate walking intensity. Most individuals believed they ought to “walk through pain”, but were uncertain what this meant. The notion of “walking through pain” was often inconceivable, and attempts at walking had produced discouraging, or perplexing, results:

“Everyone seems to be keen on the medical side of telling you to walk through it, and I thought, ‘Why’? And it only ever works very rarely. Occasionally, you go for a fairly long walk, you just keep going through the agony, and then it does ease off... Is that it?” (007A, male, 69 years).

Few participants conveyed the importance of exercise intensity, or an understanding of how to modify or monitor their walking intensity in order to improve their IC and cardiovascular health. One individual who had longstanding IC had considered but not attempted to increase his walking intensity:

“I have got to learn to pace myself, do a bit more pace work, as opposed to just strolling around.” (001A, male, 67 years)

Others who considered walking to intensity described IC as a key factor hampering their attempts:

“When you exercise, you feel as if your heart rate should go a bit, and you kind of feel almost that refreshed feeling, that exhilarated. I never get that. I just meander along with the pain beginning and getting worse and worse until I have to stop.” (008A, female, 44 years)

Limited purposeful walking for exercise

A lack of tailored walking guidance, including the potential outcomes of walking and appropriate walking intensity, meant that participants did not embark on purposeful walking

for exercise. Participants instead engaged in incidental walking, often incorporated into daily errands or tasks:

"I wouldn't choose walking as a form of just simple exercise. I would rarely, maybe occasionally, I would go out for a walk... it's either shopping, going to see somebody, in a form of transport getting somewhere." (008A, female, 44 years)

Some participants held a "more is better" attitude toward walking, encompassing the notion that the body was a "machine" that needed movement to "avoid seizing up" (128B, female, 78 years). Consequently, individuals who engaged in purposeful walking were uncertain of how much was enough:

"I'm doing an hour's walk. I used to do 2 hours, but I'm doing that and I feel that, like, I'm pushing it each day... If a doctor says to me, you know, 'look, you should do 2 hours, 3 hours a day,' I would do it. But I don't know, you see." (005A, male, 62 years)

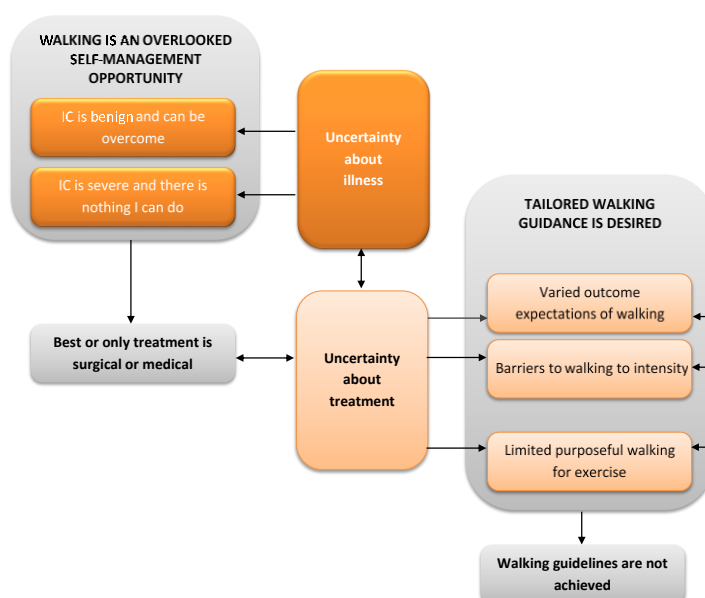
Most individuals preferred incorporating walking to their daily lives. Five participants (001A, 093B, 005A, 010A, and 011A) who described purposeful walking understood that walking could improve circulation, and viewed walking as a means of symptom management. Some individuals were inclined to try purposeful walking, and recognised barriers to doing so. One individual drew on planning and social support as potential strategies when attempting purposeful walking:

"I've got to try and get myself organised so that I go out on my own or with the wife, and so we say, 'Alright, we're going to have an hour's walk.'" (001A, male, 67 years)

5.3.3 Thematic map

From the present findings a thematic map was developed (Figure 5.1) suggesting that past experiences and treatment beliefs about walking were proximal to the fulfilment of walking guidelines. Illness beliefs about the consequences of IC resulted in walking being overlooked as a self-management opportunity, and a predominant medical model of treatment, which contributed to treatment beliefs about the role of walking. Uncertainty about walking treatment was expressed as a lack of tailored walking guidance, which resulted in varied outcome expectations of walking, barriers to walking to intensity and, as a consequence, limited purposeful walking.

Figure 5.1 Thematic map illustrating explanatory themes identified in a qualitative study exploring the experiences of and beliefs about walking and illness among 19 individuals with IC



5.3.4 Reflexive diary

MGH is an academic researcher with an educational background in exercise medicine and health psychology, and has conducted quantitative studies and qualitative focus group research involving people with IC. Clinically, she is trained in diagnosis and monitoring of PAD using Doppler ultrasound, and administered a supervised exercise programme for people with IC. A social constructivist epistemological approach was maintained during this research, which asserts that reality is socially constructed, and can be understood through language and

interpretation. The researcher acknowledges the influence of her past experiences and theoretical frameworks underpinning this body of work (i.e., TPB and CSM) in the design of this study, interaction with participants during interviews, and interpretation of data.

5.4 Discussion

This qualitative study identified two superordinate themes that help explain walking beliefs and behaviour among people with IC. First, walking is overlooked by people with IC as a self-management opportunity. Two subthemes demonstrate that self-management strategies were framed around perceived consequences of IC as relatively benign or severe, and that neither instance was resolved through walking. Second, people with IC express a desire for tailored walking guidance. Three subthemes demonstrated cognitive (e.g., uncertainty regarding the outcome of walking for IC) and experiential (e.g., tendency for incidental walking, attempts at engaging in moderate to vigorous walking) explanations for the finding that participants were not achieving guidelines for walking.

Walking is a first-line strategy for treating stable IC (NICE, 2012). However, participants did not consider walking as a treatment, centring their management options on the perceived consequences of IC and the likelihood and risk of revascularisation, thereby adhering to a medical model of treatment. These findings are consistent with a previous study, which reported prevailing beliefs that revascularisation could cure IC among individuals interviewed post-operatively (Cunningham et al., 2014). This suggests that the optimal time point for intervening to change walking behaviour may be upon diagnosis, and before individuals undergo revascularisation. However, there is no evidence that illness and walking treatment beliefs following revascularisation are particularly resistant to change, and it may be that individuals who undergo revascularisation receive greater exposure to advice from healthcare professionals regarding treatment for IC and may be better informed. For example, participants in the current study who had undergone a bypass or angioplasty recognised their role – or duty of self-care – alongside the care of their vascular specialist, in order to optimise the outcome of their treatment and prevent the need for future revascularisation. In addition,

Wann-Hansson et al. (2008) reported a desire to prevent disease progression following revascularisation as a factor influencing behaviour change among people with IC. Together, these findings suggest a wider scope for successfully intervening to facilitate a change in walking behaviour among people with IC.

Another factor explaining why many people with IC do not adopt walking as a treatment strategy might be a lack of awareness of walking guidelines. Participants in the current study reported receiving advice to walk, but none were aware of specific walking guidelines and expressed a desire for tailored instructions. Individuals adopted walking advice in the form of incidental walking that was structured around daily activities or errands. This pattern of behaviour was also reflected in responses to the physical activity questionnaire, wherein nearly half (48%) of participants reported walking for several hours a day, on most days of the week. Participants also described barriers to achieving moderate to vigorous walking, indicating they were not walking at an appropriate intensity. Daily activity level is positively associated with physical function and reduced cardiovascular morbidity among people with IC (McDermott et al., 2002; Garg et al., 2009; Garg et al., 2006), but improvements in PFWA and MWA may require progressive challenges to the vascular system as demonstrated following structured walking therapy (Lane et al., 2014). It is possible that current guidelines for walking, which are based on supervised centre-based programmes do not translate easily or realistically to home-based walking. Indeed, among participants in the current study who had previously attended supervised exercise therapy, none reported currently engaging in walking, and they identified barriers to walking including comorbidities, a lack of motivation, time constraints, and leg pain, which had not been adequately addressed in supervised programmes or by healthcare professionals. As healthcare resource limitations are likely to preclude the implementation of supervised exercise therapy, interventions which help participants to understand and engage in self-directed walking are needed.

Participants largely underestimated the potential for walking to improve their symptoms, and frequently suggested general health benefits of walking as more plausible. The TPB and CSM recognise outcome expectation and treatment efficacy, respectively, as important factors driving health behaviour. Outcome expectation reflects the behavioural belief underpinning attitude within the TPB, and is an important determinant of intention, whereas the CSM includes treatment control (i.e., the perceived efficacy of a treatment) as a key aspect of the illness representation. Therefore, ensuring positive and realistic beliefs about treatment options, including walking, might facilitate self-management among individuals with IC.

5.4.1 Methodological considerations

This study has several strengths. It includes participants with long-standing IC (>2 years), which allowed the exploration of a range of illness and treatment experiences. Participant experiences of walking as a treatment were explicitly elicited in order to broaden our understanding of the links between illness and walking treatment in this population. The study was theoretically underpinned, and adhered to a robust and systematic procedure using the Framework Method. Measures were taken to validate data, including researcher validation and member-checks with participants.

Researcher bias is an important consideration in qualitative research, and can limit the interpretation of findings where transparency is lacking; this study employed the use of reflexive diaries and field notes following interviews to recognise and acknowledge biases, and a reflexive statement is reported indicating the researcher's training, experience, and pre-existing knowledge of the theoretical frameworks and population. Transparency is facilitated by the use of the Framework Method, which permits the deductive development of themes that are informed by existing theory.

There are some limitations to this study. Participants were recruited from a vascular surgery outpatient clinic, and it is possible that people newly diagnosed with IC, and those not yet referred to a vascular specialist may express different beliefs about their condition and

treatment, which were not captured. In addition, participants predominantly (90%) identified themselves as White despite attempts to recruit people from a range of ethnicities. This is similar to other clinical studies, which have identified challenges of recruiting a representative ethnically diverse sample (Sheikh et al., 2009; Heiat et al., 2002). Future research exploring the beliefs of individuals from different cultural background could enrich our understanding of the experience of IC in these populations.

5.4.2 Conclusions

- People with IC report uncertainty regarding their PAD, IC, and the role of walking treatment, which may contribute toward a lack of engagement in walking behaviour.
- Walking is not perceived as treatment, and therefore not adopted as a self-management strategy for IC.
- Beliefs about the severity (i.e., perceived consequences) of IC contribute to inactivity, either by an associated negative emotional response, including feelings of fear and helplessness, or via a lack of perceived need for walking treatment for IC.
- Individuals with IC report a high volume of incidental walking and limited purposeful walking for exercise, which is inconsistent with existing walking treatment guidelines for IC.
- Tailored walking guidance from a healthcare professional, which explicitly addresses perceived barriers to moderate and vigorous walking (i.e., perceived behavioural control) and beliefs about the outcome of walking treatment for IC (i.e., attitude regarding walking and treatment control regarding IC) is desired, and may facilitate increased walking.

Chapter 6. Explaining walking intention and objective walking ability in individuals with IC: the role of walking treatment and illness cognitions

6.1 Introduction

People with IC engage in lower levels of walking behaviour compared with healthy, age-matched controls (Garg et al., 2009; Lauret et al., 2014), and do not achieve walking treatment guidelines for improving IC. Over an 18 month observational follow-up, Gardner et al. (2004) demonstrated that, without further intervention (e.g., medication, exercise therapy, or revascularisation), walking ability (6MWD) declines among individuals with IC by 9%, and PFWd declines by 22%. Corresponding decreases in daily walking behaviour suggest that, beyond age-related decline, changes in walking ability may be attributable to changes in walking behaviour (McDermott et al., 2006).

Psychosocial factors related to illness and walking treatment are barriers to self-management reported by people with IC, and theory-defined constructs, in particular those consistent with the TPB and CSM, are salient (Chapter 5).

To date, three studies evaluated TPB or CSM variables as determinants of walking among people with IC (Chapter 2). Walking treatment cognitions defined by the TPB explained walking intentions among individuals with IC (Galea and Bray, 2007; Galea and Bray, 2006), but the model did not consistently explain walking behaviour, and is therefore incomplete. In addition, studies did not control for past walking behaviour, an important determinant of future behaviour within the TPB (McEachan et al., 2011), which could bias responses toward current judgements about walking (Hagger et al., 2002a; Bagozzi, 1981). Illness cognitions defined by the CSM did not explain adherence to guidelines reflecting the frequency and duration of walking for IC; however, causal attributions were not evaluated, and walking was assessed using a non-validated, single-item, self-reported measure (Cunningham, 2010).

To strengthen our understanding of salient psychosocial variables that influence walking intention and behaviour in people with IC, past walking behaviour should be taken into account, and objective walking behaviour assessed. While behaviour change (e.g., programme attendance or increased self-directed walking) is a prerequisite for successful walking interventions for people with IC, the primary treatment aim includes improvements in walking ability (Norgren et al., 2007). Walking ability, ideally quantified using a validated objective measure (e.g., treadmill or corridor walk tests), provides a valuable clinical outcome, and an approximation of daily walking behaviour (McDermott et al., 2008). However, to date, no studies have explored constructs defined by the TPB or CSM, alone or in combination, as determinants of objective walking ability among people with IC.

6.1.1 Aims

The aim of this study is to evaluate the TPB and CSM together to test the utility of their constructs for explaining walking intention and objective walking ability, defined as the 6MWD, in people with IC.

6.1.2 Objectives

The objectives of this study are:

- a) to evaluate whether illness cognitions explain variance in walking intention above and beyond past walking behaviour, attitude, subjective norm, and perceived behavioural control;
- b) to evaluate whether walking intention and perceived behavioural control explain variance in 6MWD beyond past walking behaviour; and
- c) to evaluate whether illness cognitions explain variance in 6MWD beyond past walking behaviour, walking intention, and perceived behavioural control.

6.1.3 Hypotheses

Hypotheses evaluated in this study are listed in Table 6.1.

Table 6.1 Null and alternative hypotheses tested in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6 Minute Walk Distance (6MWD)

Null hypotheses		Alternative hypotheses	
H ₀ 1:	Illness cognitions will not explain variance in walking intention beyond past walking behaviour, and attitude, subjective norm, and perceived behavioural control regarding walking treatment.	H ₁ 1:	Illness cognitions will explain variance in walking intention beyond past walking behaviour, and attitude, subjective norm, and perceived behavioural control regarding walking treatment.
H ₀ 2:	Perceived behavioural control and walking intention will not explain variance in 6MWD beyond past walking behaviour.	H ₁ 2:	Perceived behavioural control and walking intention will explain variance in 6MWD beyond past walking behaviour.
H ₀ 3:	Illness cognitions will not explain variance in 6MWD beyond past walking behaviour, perceived behavioural control, and walking intention.	H ₁ 3:	Illness cognitions will explain variance in 6MWD beyond past walking behaviour, perceived behavioural control, and walking intention.

6.2 Methods

6.2.1 Study design

A cross-sectional observational study was conducted.

6.2.2 Ethical approval

Ethical approval was obtained on 30 August 2011 from NRES Committee London – London Bridge (reference 11/LO/0871) (Appendix 1). Approval from the Department of Research and Development, Guy's & St Thomas' NHS Foundation Trust was confirmed on 12 September 2011 and from King's College Hospital NHS Foundation Trust on 31 January 2013 (CSP reference 73416).

6.2.3 Eligibility criteria

Participants met the following inclusion criteria:

- 1) adults aged ≥ 18 years; and
- 2) IC diagnosed by a vascular clinician, and based on results of established methods (e.g., ABPI, duplex ultrasound, computed tomography, magnetic resonance imaging) against recommended criteria (Norgren et al., 2007).

Exclusion criteria were:

- 1) revascularisation (e.g., endovascular treatment or bypass surgery) scheduled in the upcoming 3 months;
- 2) the presence of a comorbidity other than IC (e.g., knee osteoarthritis, back pain) self-reported as the primary limitation of walking;
- 3) the presence of a condition for which it is inadvisable to increase walking (e.g., unstable angina); and/or
- 4) inability or refusal to provide informed consent.

6.2.4 Sampling and recruitment

Sample size calculation

Sample size was calculated *a priori* by a standard power calculation. Using G*Power software (version 3.1.9.2) (Faul et al., 2009), a medium effect ($f^2=0.15$, equivalent to $R^2=0.13$) in variance of 6MWD with $\alpha=0.05$, a power of 0.80, and including 15 predictor variables required 139 participants. To account for a maximum rate of missing data of 10% (Roth, 1994), the target sample size was increased to 153 participants.

Participant recruitment

Participants were identified from vascular outpatient clinics at Guy's & St Thomas' NHS Foundation Trust between 1 September 2011 and 15 July 2014 and from King's College Hospital NHS Foundation Trust between 1 February 2013 and 15 July 2014.

Medical records of individuals attending vascular outpatient clinic appointments were screened for eligibility by the direct healthcare team, and potential participants were identified and informed of the study. Eligible individuals who expressed an interest in the study were provided with further verbal and written information by the researcher (MGH), and contact details were obtained. After at least 24 hours, the potential participant was telephoned and invited to attend a single appointment at a mutually convenient time. If they agreed to attend, a confirmation letter provided details of the scheduled appointment and directions to the site, or of transportation provided. Participants received a reminder telephone call within 2 days of their scheduled appointment.

6.2.5 Outcome measures

Sociodemographic and clinical characteristics. The following variables were assessed by self-report: age, gender, marital status (never married, married, separated, divorced, or widowed) ethnicity (White, mixed/multiple ethnic background, Asian/Asian British, Black/African/Caribbean/Black British, or other), smoking status (current, previous, or never), presence of comorbidities (diabetes mellitus, cholesterol, hypertension, cardiovascular disease, renal disease, previous heart attack, or stroke), current medication for IC (yes/no), other mobility-limiting symptoms or conditions (yes/no), and participation in an exercise programme in the past 3 years (yes/no) (Appendix 5).

Walking, theory-based constructs, and descriptive clinical variables were assessed and are described in full in Chapter 3 (Table 6.2).

Table 6.2 Outcome measures included in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD

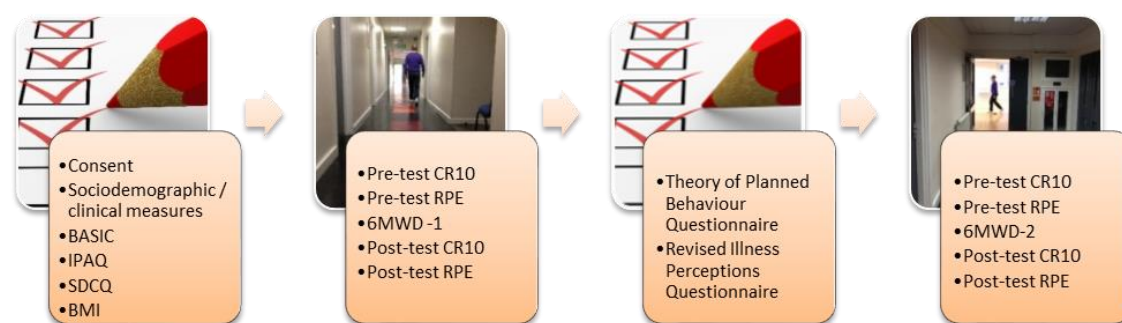
Variable	Measure
Objective walking ability	
6 Minute Walk Distance (6MWD)	6 Minute Walk Test (6MWT)
Pain-Free Walking Ability (PFWA)	6MWT
Maximal Walking Ability (MWA)	6MWT
Walking behaviour	
Self-reported walking behaviour	Baltimore Activity Scale for Intermittent Claudication (BASIC)
Past walking behaviour	International Physical Activity Questionnaire (IPAQ)
Theory-based constructs	
Walking treatment cognitions	Theory of Planned Behaviour Questionnaire (TPB)
Illness cognitions	Revised Illness Perception Questionnaire (IPQ-R)
Descriptive clinical variables	
Lower-limb symptom classification	San Diego Claudication Questionnaire (SDCQ)
Health-related quality of life	Medical Outcomes Survey Short Form-12 version 2 (SF-12v2)
Perceived activity intensity	Borg Rating of Perceived Exertion (RPE)
Perceived pain intensity	Borg Category–Ratio 10 Scale for Pain (CR10)
Body mass index (BMI)	Standard scales

6.2.6 Procedure

Participants were invited to attend a 1.5 hour session at the Division of Health and Social Care Research, King's College London (London, UK). Upon arrival, participants were seated in a quiet meeting room, asked if they had read the information letter and invited to ask any questions. Participants were asked to read, complete and sign three copies of the consent form, one which was retained by the researcher, one which was filed in the participants' medical records, and the other provided to the participant for their own reference. Questionnaires assessing sociodemographic variables, the BASIC, and the IPAQ were completed in that order. The researcher then administered the SDCQ and measured participants' BMI.

Next, participants received standardised instructions on the 6MWT and completed the CR10 and RPE scales prior to commencing the 6MWT (Chapter 3). At the end of the 6MWT the CR10 and RPE were re-administered. Participants rested for at least 20 minutes, during which they completed the IPQ-R and TPB questionnaires. Finally, the second 6MWT was repeated with pre- and post-test administrations of the Borg CR10 and RPE (Figure 6.1).

Figure 6.1 Flow diagram illustrating procedure of a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6 Minute Walk Distance (6MWD)



BASIC, Baltimore Activity Scale for Intermittent Claudication; BMI, body mass index; CR10, Category–Ratio 10 Scale for Pain; IPAQ, International Physical Activity Questionnaire; IPQ-R, Revised Illness Perception Questionnaire; RPE, Rating of Perceived Exertion; SDCQ, San Diego Claudication Questionnaire; TPB, Theory of Planned Behaviour; 6MWD, 6 Minute Walk Distance.

6.2.7 Analyses

Statistical analyses were carried out in SPSS Statistics Software version 21.0 (IBM Statistics Inc., Armonk, NY, USA). Statistical significance was set at $p < 0.05$.

Data preparation and scale exploration

Internal consistency of all self-reported measures was evaluated by using Cronbach's α . Scores were interpreted as ≥ 0.70 =good, 0.60 – 0.69 =acceptable, 0.50 – 0.59 =poor, and <0.50 =unacceptable reliability (Cronbach, 1951).

Data were examined for missing values. Participants missing $>10\%$ of data at the item level were excluded from analyses. For all scales, except the IPQ-R, mean substitution was used to derive missing data before summary scores were computed (Roth, 1994). For scales reflecting IPQ-R variables, summary scores were computed as recommended (Chapter 3) (Weinman et al., 2000; Moss-Morris et al., 2002).

Descriptive analyses

Sociodemographic and clinical characteristics are presented as means \pm SD or 95% CIs for continuous variables, and frequencies (%) for categorical variables. MD scores (95% CI) are presented for pre- and post-test reports of perceived pain intensity (CR10) and perceived activity intensity (RPE) obtained during the second 6MWT, and for the 6MWD obtained during the first and second 6MWTs.

Distributions of outcome measures were explored for normality by visual inspection of histograms and normal Q-Q plots, and calculating standardised scores for skewness (z_s) and kurtosis (z_k). Scores for z_s and z_k >1.96 or <-1.96 were defined as departures for normality (Field, 2013). \log_{10} and square root transformations were applied to raw or reflected scores for data that were positively or negatively skewed, respectively. The method producing the best approximation of normality for a given variable was retained for analyses of that variable (Tabachnick and Fidell, 2013). Non-normal data were transformed to their original scales to aid the interpretation of results.

Bivariate relationships between past walking behaviour, CSM, and TPB variables, and the criterion variable for each model (i.e., walking intention or 6MWD) were explored using two-sided Pearson correlation coefficients.

Hypothesis testing

Hypotheses were evaluated using two hierarchical multiple linear regression analyses. Each regression model included three blocks. The adjusted multiple regression coefficient (R^2_{adj}) for the final model, and R^2 change ($R^2\Delta$) for each block of the model are reported. Standardised β coefficients are reported for the independent variables. In each model, past behaviour was controlled for in the first block of the regression analyses because it reflects a variable that temporally precedes the main TPB constructs, and has been shown to independently contribute toward explaining physical activity intention and behaviour (McEachan et al., 2011; Sutton, 2005). TPB variables were entered in the second block, before illness cognitions, because 1) past research has demonstrated a large effect of TPB variables on walking intention in individuals with IC (Galea and Bray, 2007; Galea and Bray, 2006); and 2) it is recommended that research on health behaviour explore the utility of general theories of behaviour change initially (e.g., TPB), and apply health-specific theories (e.g., CSM) only if they improve our understanding of behaviour change (Sutton, 2005). In block three, illness cognitions were included in order to explore their utility in explaining intention above and beyond TPB constructs.

Model 1

The first three-block multiple linear regression model tested the first hypothesis (H_{11}) (Table 6.3).

Table 6.3 Structure of a hierarchical multiple linear regression model evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of walking intention

Block (Enter)	Variables
1. Past walking behaviour	7-Day walking frequency
2. Walking treatment cognitions	Attitude Subjective norm Perceived behavioural control
3. Illness cognitions	Identity Personal control Treatment control Consequences Coherence Acute timeline Cyclical timeline Emotion Psychological attributions Risk factors attributions Immunity attributions Accident/chance attributions

Model 2

The second three-block multiple linear regression model tested the second (H_{12}) and third (H_{13}) hypotheses (Table 6.4). Blocks 1 and 2 tested H_{12} , and Block 3 tested H_{13} .

Table 6.4 Structure of hierarchical multiple linear regression model evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of 6MWD

Block (Enter)	Variables
1. Past walking behaviour	7-Day walking frequency
2. Walking treatment cognitions	Perceived behavioural control Intention
3. Illness cognitions	Identity Personal control Treatment control Consequences Coherence Acute timeline Cyclical timeline Emotion Psychological attributions Risk factors attributions Past behaviour attributions Accident/chance attributions

Criteria for meeting the assumptions of multiple linear regression analyses

Multicollinearity. Criteria for absence of multicollinearity required bivariate correlations between predictor variables <0.80, variance inflation factors <10.0, and tolerance statistics <0.10 (Tabachnick and Fidell, 2013).

Homoscedasticity. Constant variance between predicted dependent variable scores and errors of prediction required a random distribution of scores based on visual examination of a scatterplot of standardised residual values against standardised predicted values of the dependent variable.

Normality of the error distribution. A normal distribution of the frequency of standardised residual scores around the predicted dependent variable scores was determined by visual evaluation, a mean of the distribution approaching zero, and no deviations from normality based on Normal P–P plots of standardised residuals.

Independent errors. The criterion for independent residual terms between observations was a Durbin–Watson statistic <1 or >3.

Absence of outliers in the model. Univariate outliers were defined as Studentised residual values ± 3 SD. Multivariate outliers were defined as a Mahalanobis distance (Mahal D^2) greater than the critical value of χ^2 for the degrees of freedom of the final model at $p=0.01$ (Field, 2013).

6.3 Results

6.3.1 Participant characteristics

Overall, 152 individuals with IC were enrolled onto the study. One participant (022B, male, age not reported) withdrew from the study during questionnaire completion, 6 participants had >10% missing data at the item level (range 17.3–22.2%) and were excluded from analyses, and 3 participants were identified as outliers (Section 6.3.6). Therefore, data for 142 individuals were included in the analyses. Sociodemographic and clinical characteristics of excluded participants did not differ substantially compared with data for included participants.

The majority of included participants were male (80%) and White (80%) (Table 6.5). Just over one-third (35%) of participants were currently smoking, and nearly one-quarter (24%) had attended a supervised exercise programme for IC within the previous 3 years. Classic IC was the most common symptomology (48%), followed by atypical exertional leg symptoms (37%). One-half (50%) of participants with available data had been managed conservatively.

Table 6.5 Sociodemographic and clinical characteristics of participants in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD

Variable	Value, n (%)
Age, years	66.9 ±10.2 ^a
Body mass index, kg/m ²	28.2 ±5.0 ^a
Male gender	116 (80.0)
Married	61 (42.1)
White ethnicity	116 (80.0)
Current smoker	51 (35.2)
Cardiovascular risk factors	
Diabetes mellitus	50 (34.5)
Cardiovascular disease ^b	63 (43.8)
Hypertension	105 (72.4)
Hyperlipidaemia	101 (69.7)
Renal disease ^b	14 (9.7)
Past heart attack	31 (21.4)
Past stroke ^b	22 (15.2)
Comorbid pain	53 (36.6)
Pharmacological IC management	44 (30.3)
Past supervised exercise therapy	35 (24.1)
Past revascularisation ^c	
None	72 (49.6)
Angioplasty (with or without stent)	21 (14.5)
Bypass surgery	9 (6.2)
Endarterectomy	2 (1.4)
Multiple procedures	2 (1.4)
Lower-limb symptom classification	
No pain	2 (1.4)
Pain at rest	20 (13.8)
Classic IC	69 (47.6)
Atypical IC	54 (37.2)

n=142. ^aData are mean ±SD. ^bData are missing for one participant. ^cData are missing for 39 participants. IC, intermittent claudication.

6.3.2 Scale reliability

Inter-item reliability was demonstrated by Cronbach's α scores ranging from 0.63–0.91, except for accident/chance attributions (IPQ-R), which had a Cronbach's α score of 0.34. This is consistent with previous research (Moss-Morris et al., 2002) and attributable to a 2-item scale, so despite the low reliability, the scale was retained for further analyses (Table 6.6).

Table 6.6 Inter-item reliability of psychometric scales of the Theory of Planned Behaviour and Revised Illness Perception Questionnaires

Questionnaire and scale	Cronbach's α
Theory of Planned Behaviour Questionnaire	
Attitude	0.83
Subjective norm	0.82
Perceived behavioural control	0.74
Walking intention	0.91
Revised Illness Perception Questionnaire	
Personal control	0.64 ^a
Treatment control	0.69
Consequences	0.65 ^b
Coherence	0.79 ^c
Acute timeline	0.76 ^c
Cyclical timeline	0.76
Emotion	0.83 ^c
Psychological attributions	0.83 ^d
Risk factor attributions	0.64 ^a
Immunity attributions	0.76 ^e
Accident/chance attributions	0.36 ^{c,f}

Data reflect n=142 with the following exceptions: ^an=139; ^bn=140; ^cn=141; ^dn=134; and ^en=135. ^fLow internal consistency was attributed to a 2-item scale, and the variable was retained in the model.

6.3.3 Missing value analyses and treatment

There was a high frequency of item-level missing data across participants for the IPAQ, ranging from 1 (0.7%, item 1, days of vigorous physical activity) to 17 (11.3%, item 4, duration of moderate physical activity). There was also a high frequency of responses coded as “don't know/not sure” for item 2 (duration of vigorous physical activity), item 4 (duration of

moderate physical activity), and item 6 (duration of walking). There were no missing data for item 5, reflecting walking frequency, which was used in regression analyses to reflect past walking behaviour.

Among variables included in the regression models, the rate of missing data was <5% (Appendix 5). Overall, 29 participants were missing data (all <10% at the item level). There were no clear patterns across missing data, with the exception of one item reflecting subjective norm (n=5 missing, “My spouse/significant other approves of me doing the recommended walking exercise”) and four items reflecting causal attributions (pollution in the environment [n=2 missing], family problems or worries [n=2 missing], my own personality [n=4 missing], and altered immunity [n=5 missing]).

6.3.4 Data distributions and transformations

All data were normally distributed except variables reflecting past walking behaviour (IPAQ), subjective norm (TPB), walking intention (TPB), accident/chance attributions (IPQ-R), and identity (IPQ-R), which were transformed (Table 6.7)

Table 6.7 Summary of data transformations for non-normally distributed variables included in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD

Variable	Distribution	Transformation	Formula
Past walking behaviour (PWB)	Severe negative skew	Reflect and logarithm	$\text{Log(PWB)} = \text{LG10}(8 - \text{PWB})$
Subjective norm (SN)	Severe negative skew	Square root	$\text{SQRT(SN)} = \text{SQRT}(29 - \text{SN})$
Intention (INT)	Severe negative skew	Reflect and logarithm	$\text{Log(INT)} = \text{LG10}(29 - \text{INT})$
Accident/chance attributions (AC)	Moderate positive skew	Square root	$\text{SQRT(AC)} = \text{SQRT(AC)}$
Identity (ID)	Negative skew	Square root	$\text{SQRT(ID)} = \text{SQRT}(\text{ID} + 1)$

6.3.6 Descriptive results

Objective walking ability

Mean 6MWD was 365.0 metres (95% CI 347.3, 382.7; range 62.2–581.2). Pain intensity scores increased by mean 3.7 (95% CI 3.3, 4.0) and perceived exertion by mean 5.02 (95% CI 4.5, 5.5). Post-test scores reflect pain intensity that is “somewhat severe to severe” and a perceived exertion that is “light to somewhat hard”.

Overall, 75 (52%) participants reported their PFWA (mean 128.4 seconds [95% CI 114.0, 143.0]) and 36 participants stopped to rest during the walk test (MWA; mean 185.9 seconds, 95% CI 154.8, 216.9) (Table 6.7).

Table 6.7 Data reflecting objective walking ability and descriptive clinical variables measured during the 6 Minute Walk Test (6MWT) in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD

Variable	Mean \pm SD	95% CI
6 Minute Walk Distance, metres	365.0 \pm 107.8	347.3, 382.7
Pain-Free Walking Ability, seconds	128.4 \pm 63.0	114.0, 143.0
Maximal Walking Ability, seconds	185.9 \pm 91.8	154.8, 216.9
Pre-test perceived activity intensity	7.7 \pm 2.7	7.3, 8.2
Post-test perceived activity intensity	12.8 \pm 3.1	12.3, 13.3
Pre-test perceived pain intensity	0.8 \pm 1.2	0.6, 1.0
Post-test perceived pain intensity	4.5 \pm 2.3	4.1, 4.9

n=142 except Pain Free Walking ability (n=75) and Maximal Walking Ability (n=36).

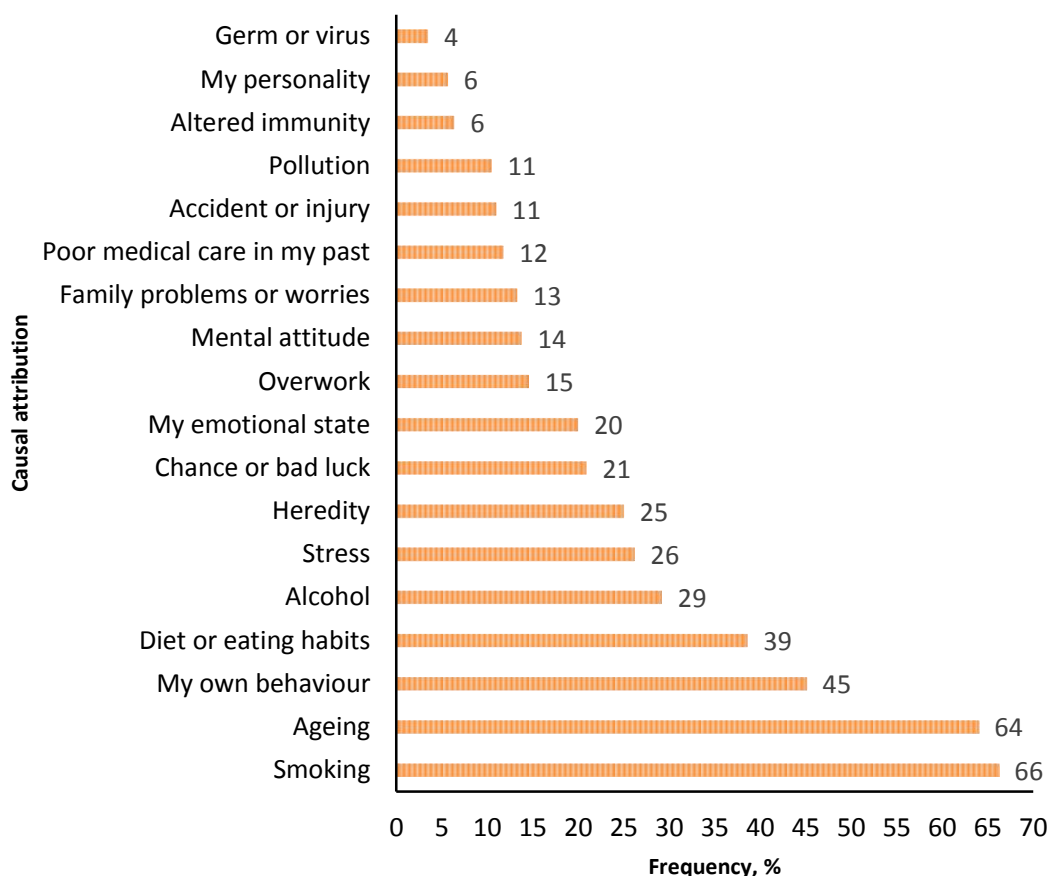
Participants walked 12.94 metres (95% CI 7.30, 18.6) further during the second 6MWT compared with the first, which suggested a small learning effect (3.5%) (American Thoracic Society, 2002).

Perceived causal attributions

Overall, risk factors were the predominant causal attributions (assessed using the IPQ-R), and the most frequently reported single causal attribution was smoking (66.2%). Over one-quarter

of participants also agreed that ageing, their own behaviour, dietary behaviour, alcohol, and heredity were likely causes of their PAD. Stress was the only other causal attribution reported by more than 25% of the sample (Figure 6.2 and Appendix 5)

Figure 6.2 Frequencies of perceived causal attributions of PAD reported by participants in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD



Descriptive statistics and bivariate correlations for psychosocial predictors and criterion variables are presented in Table 6.8. Mean scores were positive for all TPB variables, and for personal control, treatment control, coherence and risk factor attribution regarding PAD. PAD was perceived as acute, and with high consequences and emotional impact. Bivariate associations were, overall, in the anticipated directions. 6MWD was positively associated with all TPB variables ($r=0.17$ – 0.38), and with personal control ($r=0.38$), coherence ($r=0.32$), and risk

factor attribution (0.18), and negatively associated with acute timeline ($r=-0.16$), consequences ($r=-0.26$), and emotion ($r=-0.22$). Walking intention was positively associated with other TPB variables ($r=0.67-0.75$), and with treatment control ($r=0.20$), personal control ($r=0.19$) and coherence ($r=0.21$), and negatively associated with acute timeline ($r=-0.23$) and accident/chance attributions ($r=-0.17$). Treatment control and personal control were positively associated with all TPB variables ($r=0.16-0.25$), whereas high and low scores for coherence ($r=0.21-0.23$) and consequence ($r=-0.22-0.30$), respectively, were associated with attitude and perceived behavioural control, but not subjective norm. Acute timeline was associated with low scores for attitude ($r=-0.29$) and subjective norm ($r=-0.20$), and accident/chance attributions were associated with low scores for subjective norm ($r=-0.14$) and perceived behavioural control ($r=-0.22$).

Table 6.8 Descriptive statistics and bivariate correlations between past walking behaviour, walking treatment cognitions, illness cognitions, walking intention, and 6MWD

Variable	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	M	SD
1. Attitude	0.57 ^a	0.65 ^a	0.13	-0.29 ^a	-0.10	0.21 ^a	0.29 ^a	0.21 ^b	-0.30 ^a	-0.02	-0.05	-0.10	0.05	0.14	0.37 ^a	0.67 ^a	0.38 ^a	44.9	9.7
2. Subjective norm		0.58 ^a	0.04	-0.20 ^b	-0.10	0.25 ^a	0.21 ^b	0.18	0.02	-0.10	0.01	-0.11	-0.16 ^b	0.11	0.25 ^a	0.75 ^a	0.17 ^b	23.0 ^c	10.0 ^c
3. PBC			0.11	-0.14	-0.18	0.16 ^a	0.25 ^a	0.23 ^b	-0.22 ^a	-0.16	0.04	-0.19	-0.22 ^a	-0.12	0.43 ^a	0.72 ^a	0.27 ^a	31.9	7.2
4. Identity				-0.19 ^a	-0.26 ^a	0.17	0.12	0.17	-0.40 ^a	-0.32 ^a	-0.15	-0.18 ^b	0.14	-0.45 ^b	0.11	0.03	0.16	3.0 ^c	4.0 ^c
5. Acute timeline ^b					0.4	-0.44 ^a	-0.31 ^a	-0.11	0.33 ^a	0.01	0.29 ^a	-0.08	-0.08	0.18 ^b	-0.07	-0.23 ^a	-0.16 ^b	19.9	4.3
6. Cyclical timeline ^b						-0.06	-0.06	-0.50 ^a	0.08	0.32 ^a	0.04	0.30 ^a	-0.27 ^a	0.17	-0.04	-0.08	-0.11	11.6	3.5
7. Treatment control							0.49 ^a	0.14	-0.16 ^b	0.02	0.07	0.08	0.04	-0.12	-0.11	0.20 ^b	0.05	17.5	3.7
8. Personal control								0.25 ^a	-0.35 ^a	0.02	0.17 ^b	0.01	0.14	-0.31 ^a	0.09	0.19 ^b	0.38 ^a	20.1	3.7
9. Coherence									-0.20 ^b	-0.31 ^a	0.04	-0.29 ^a	0.22 ^b	-0.26 ^a	0.10	0.21 ^b	0.32 ^a	16.9	4.0
10. Consequences ^b										0.24 ^a	0.20 ^b	0.14	-0.17 ^b	0.64 ^a	-0.13	-0.01	-0.26 ^a	19.4	4.3
11. Psychological attributions ^a											0.28 ^a	0.69 ^a	-0.42 ^a	0.39 ^a	-0.11	-0.08	-0.12	13.7	4.6
12. Risk factor attributions												0.25 ^a	-0.08	0.20 ^b	0.08	-0.02	0.18 ^b	20.5	4.5
13. Immunity attributions ^b													-0.53 ^a	0.19 ^b	-0.06	-0.13	0.01	6.5	2.2
14. Accident/chance attributions ^b														-0.17 ^b	0.07	-0.17 ^b	-0.06	4.0 ^c	2.0 ^c
15. Emotion ^b															-0.08	0.09	-0.22 ^a	17.4	5.6
16. Past walking behaviour																0.41 ^a	0.33 ^a	5.0 ^c	5.0 ^c
17. Walking intention																	0.26 ^a	25.0 ^c	9.0 ^c
18. 6MWD, metres																		367.0	107.0

n=142. ^ap<0.01. ^bp<0.05. ^cData are median (IQR) for variables transformed to their original scales. ^bA lower score indicates a more positive or accurate illness perception. M, mean; PBC, perceived behavioural control; SD, standard deviation; 6MWD, 6 Minute Walk Distance.

6.3.7 Hierarchical multiple linear regression analyses

Tests of assumptions of multiple linear regression

Assumptions for the absence of multicollinearity, and for normality, linearity and homoscedasticity between predicted dependent variable scores and errors of prediction were met for both regression models (Appendix 5). There were no univariate outliers. Three multivariate outliers were detected and were removed from analyses: case 14 Mahal $D^2=22.67$ (walking intention) and 22.25 (6MWD), case 71 Mahal $D^2=22.76$ (6MWD), and case 83 Mahal $D^2=29.20$ (walking intention), all $p<0.01$.

H₁1: Illness cognitions will explain variance in walking intention beyond past walking behaviour, and attitude, subjective norm, and perceived behavioural control regarding walking treatment

Intention was regressed onto past walking behaviour (Block 1), attitude, subjective norm, and perceived behavioural control (Block 2), and identity, acute timeline, cyclical timeline, treatment control, personal control, coherence, consequences, and causal attributions reflecting psychological factors, risk factors, immunity, and accident/chance (Block 3) (Table 6.9). Past walking behaviour accounted for 17% of the variance in walking intention, $\Delta F(1, 140)=27.56$ ($p<0.001$). The addition of the TPB variables in block two explained an additional 55% of the variance, $\Delta F(3, 137)=89.54$ ($p<0.001$), with attitude, subjective norm and perceived behavioural control all making significant contributions. Past walking behaviour became non-significant in this block. The addition of illness cognitions in block three accounted for an additional, but nonsignificant, 4% of variance, $\Delta F(12, 125)=1.633$ ($p=0.090$). The final regression model explained 73% of variance in walking intention, $F(16, 125)=24.21$ ($p<0.001$). Attitude, subjective norm, and perceived behavioural control were significant predictors, as was perceived consequences from the CSM (Table 6.9).

Table 6.9 Results of a hierarchical multiple linear regression evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of walking intention

Variables entered	R ² adj	R ² Δ	β	t	p-value
Block 1	0.16	0.17			<0.001
Past walking behaviour			0.41	5.25	<0.001
Block 2	0.71	0.55			<0.001
Past walking behaviour			0.09	1.81	0.059
Attitude			0.18	2.90	0.004
Subjective norm			0.45	7.68	<0.001
Perceived behavioural control			0.30	4.63	<0.001
Block 3	0.73	0.04			0.090
Past walking behaviour			0.10	1.92	0.074
Attitude			0.23	3.42	0.001
Subjective norm			0.35	5.61	<0.001
Perceived behavioural control			0.34	5.16	<0.001
Identity ^a			0.01	0.20	0.845
Acute timeline ^a			-0.06	-1.12	0.267
Cyclical timeline ^a			0.09	1.62	0.107
Treatment control			0.02	0.33	0.742
Personal control			-0.02	-0.30	0.763
Coherence			0.09	1.64	0.104
Consequences ^a			0.15	2.37	0.020
Psychological attributions			-0.01	-0.09	0.929
Risk factor attributions			-0.06	-1.18	0.240
Immunity attributions ^a			0.01	0.19	0.852
Accident/chance attributions ^a			0.06	1.12	0.266
Emotion ^a			0.08	1.24	0.218

n=142. ^aA lower score indicates a more positive or accurate illness perception.

H₁₂: Perceived behavioural control and walking intention will explain variance in 6MWD beyond past walking behaviour

6MWD was regressed onto past walking behaviour (Block 1), intention, and perceived behavioural control (Block 2). Past walking behaviour accounted for 11% of variance in 6MWD, $\Delta F(1, 140)=16.99$ ($p<0.001$). The addition of the TPB variables in block two explained an

additional, but non-significant, 2% of variance, $\Delta F(2, 138)=1.95$ ($p=0.147$). The final regression model explained 11% of the variance in 6MWD, $F(3, 138)=7.040$ ($p<0.001$). Only past walking behaviour was a significant predictor (Table 6.10).

Table 6.10 Results of a hierarchical multiple linear regression analysis evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of 6MWD

Variables entered	R ² adj	R ² Δ	β	t	p-value
Block 1	0.10	0.11			<0.001
Past walking behaviour			0.33	4.12	<0.001
Block 2	0.11	0.02			0.147
Past walking behaviour			0.25	2.81	0.006
Perceived behavioural control			0.10	0.88	0.387
Walking intention			0.09	0.75	0.453
Block 3	0.28	0.23			<0.001
Past walking behaviour			0.15	1.81	0.073
Perceived behavioural control			-0.03	-0.30	0.768
Walking intention			0.17	1.48	0.144
Identity ^a			0.04	0.52	0.607
Acute timeline ^a			-0.10	-1.02	0.308
Cyclical timeline ^a			0.02	0.17	0.868
Treatment control			-0.23	-2.45	0.015
Personal control			0.31	3.28	0.001
Coherence			0.19	2.08	0.040
Consequences ^a			-0.10	-0.95	0.345
Psychological attributions ^a			-0.18	-1.59	0.114
Risk factor attributions			0.19	2.21	0.029
Immunity attributions ^a			0.17	1.48	0.140
Accident/chance attributions ^a			0.05	0.52	0.607
Emotion ^a			-0.03	-0.28	0.780

n=142. ^aA lower score indicates a more positive or accurate illness perception.

H₁₃: Illness cognitions will explain variance in 6MWD beyond past walking behaviour, perceived behavioural control, and walking intention

Illness cognitions were added to the model testing H₁₂ (Block 3). CSM variables accounted for an additional 23% of variance in 6MWD, $\Delta F(12, 126)=3.72$ ($p<0.001$) Past walking behaviour became non-significant in this block. The final regression model explained 28% of the variance in 6MWD, $F(15, 126)=4.71$ ($p<0.001$). Treatment control, personal control, coherence, and risk factor attributions were significant predictors (Table 6.10). Unstandardised beta coefficients indicated that for every 1 unit increase in scores reflecting treatment control, personal control, coherence, and risk factor attributions, 6MWD decreased by 7.8 metres (95% CI -14.0, -1.5), and increased by 9.0 metres (95% CI 3.6, 14.5), 5.0 metres (95% CI 0.2, 9.7), and 4.6 metres (95% CI 0.5, 8.7), respectively.

6.4 Discussion

This study demonstrated that illness and walking treatment beliefs defined by the CSM and TPB contributed differently to walking intention and objective walking ability (6MWD) among individuals with IC. Attitude, subjective norm, and perceived behavioural control regarding walking (TPB) explained intention, but not walking ability. By contrast, treatment control, personal control and coherence regarding PAD, and risk factor attributions (CSM) explained objective walking ability, however, illness cognitions made no significant overall contribution to variance in walking intention beyond TPB constructs.

This is the first study to evaluate constructs from both the TPB and CSM to explain walking intention in people with IC, and the first to evaluate their relative and combined contributions to an objective measure of walking. It builds on the existing literature (Galea and Bray, 2007; Galea and Bray, 2006) by including a larger sample size and controlling for past walking behaviour. This study confirmed that TPB cognitions and past walking behaviour account for most (71%) of the variance in walking intention. The contribution of past walking behaviour on intention was reduced to a small, non-significant effect ($\beta=0.09$ $p=0.073$) with the addition of TPB variables. While this study did not aim to evaluate the mechanism for effects of past walking behaviour (e.g., mediation or moderation via TPB variables), findings suggest that participants' walking intention was influenced by reasoned, prospective cognition, and so individuals with IC might benefit from interventions that facilitate deliberate walking plans.

Among TPB cognitions, subjective norm accounted for the largest independent effect on walking intention, followed by perceived behavioural control and then attitude. This is consistent with other work exploring the TPB in IC (Galea and Bray, 2007), but contrary to research on exercise and physical activity in healthy individuals, wherein subjective norm is consistently the weakest predictor of intention (Hagger et al., 2002b). The relative importance of TPB variables can vary depending on the context, population, or behavioural outcome (Ajzen, 1991), and it may be that, among people with IC, perceptions about key referents are particularly important. Findings from this study suggest that injunctive norms regarding one's medical practitioner, spouse or significant other, and closest family member or friend, are

salient among people with IC, and that these individuals could form a network providing support that could be harnessed by interventions to facilitate walking.

This is the first study to explore illness cognitions defined by the CSM as determinants of walking intention in people with IC. CSM constructs explained only approximately 4% additional variance in walking intention beyond past walking behaviour and TPB constructs. While CSM constructs collectively did not explain walking intention, perceived consequences of PAD emerged as an independent illness cognition that contributed to walking intention alongside attitude, subjective norm, and perceived behavioural control. Findings suggest that this particular aspect of the illness representation may be salient when forming plans to engage in walking, but conflict with qualitative evidence suggesting that individuals do not consider walking as a self-management opportunity regardless of the perceived consequences of their IC (Chapter 5). However, the bivariate association between perceived consequences was small and inverse ($r=-0.007$), and suggests that a degree of multicollinearity may account for the effect noted in the multivariate model, although criteria for this assumption were met.

Illness cognitions were associated with walking ability and explained 24% of variance in 6MWD. Personal control, coherence, and risk factor attributions were independent determinants of 6MWD. Treatment control was inversely associated with 6MWD, suggesting that individuals who perceived their treatment could cure their IC were less likely to engage in walking. Qualitative evidence suggests that people with IC do not perceive walking as treatment, and frame their treatment options around medical or surgical management (Chapter 5), so it may be that individuals considered revascularisation, but not walking, when responding to items on treatment control in the IPQ-R. This suggests that individuals who believe that revascularisation could improve or cure their IC, are less likely to engage in walking.

Perceived behavioural control and walking intention explained only 2% ($p=0.147$) of variance in 6MWD. Findings are consistent with the “intention–behaviour gap”, wherein positive intention does not consistently explain behaviour (Orbell and Sheeran, 1998). Measurement

incompatibility between intention, which explored participants' self-reported plans to walk, and the outcome, which approximated walking behaviour using an objective assessment, could explain these findings. However, the 6MWD provides a validated, clinically relevant assessment of objective physical activity in people with IC (McDermott et al., 2008), and might better reflect their actual walking behaviour than self-reported measures.

Perceived behavioural control is an important predictor of self-reported walking among individuals with IC (Galea and Bray, 2007; Galea and Bray, 2006), but did not explain 6MWD. Participants might have held inaccurate control and confidence beliefs regarding walking, or anticipated general barriers to walking (e.g., lack of time or motivation), regardless of their walking ability. Perceived behavioural control best predicts behaviour when it approximates actual control. One strategy for better approximating actual control could be to prompt individuals to consider potential barriers to walking. Rejeski et al. (2008) reported a linear trend between scores reflecting barrier self-efficacy and the 6MWD among 205 people with IC. A significant difference was reported between those with poorest walking ability (<976 feet) and those who walked furthest (>1,285 feet; $p=0.0005$). However, items on the barrier self-efficacy scale used in that study reflect common challenges to being physically active, and not barriers specific to IC, nor beliefs about treatment (i.e., walking for IC) *per se*. Disease-specific measures might provide a better understanding of the impact of perceived barriers on walking. Nevertheless, findings suggest that measures of perceived behavioural control that include explicit prompts of barriers to walking might improve the explained variance in 6MWD.

6.4.1 Methodological considerations

This study has several strengths. It is the first study to evaluate constructs from the TPB and CSM together using regression analyses to explain objective walking ability, and the first to do so in people with IC. The 6MWD is a valid and reliable measure of walking, and a clinically relevant outcome for people with IC. A large, diverse, and representative sample of 145 individuals was included, which enabled fully powered hypothesis testing.

This study identifies salient cognitions that explain walking intention and objective walking ability among people with IC. However, the cross-sectional design only infers causal pathways

between variables, and it is possible that greater walking ability leads to more positive beliefs about walking and PAD. The order of outcome measurement was carefully considered to minimise participant burden (e.g., interspersing questionnaire completion between 6MWTs to reduce questionnaire fatigue and total assessment time). However, the initial 6MWT was carried out before completing surveys about illness and walking treatment cognitions, and might have primed individuals to consider their perceived walking ability when responding to subsequent surveys. However, it is unlikely that this would introduce a methodological bias (e.g., inflated covariance between predictor and criterion variables) because the initial 6MWD was not evaluated as the criterion and the context and source of 6MWD data (e.g., objective, rated by investigator) differed from that of the survey completion (e.g., subjective, self-reported) (Podsakoff et al., 2003). A standardised protocol was followed, and a baseline 6MWT was conducted to control for a learning effect, which typically ranges between 0% and 17% (American Thoracic Society, 2002). The difference (3.5% between the two 6MWTs) was small, and unlikely to be clinically meaningful.

6.4.2 Conclusions

- Illness cognitions did not explain variance in walking intention beyond past walking behaviour, and attitude, subjective norm, and perceived behavioural control regarding walking treatment.
- Perceived behavioural control and walking intention did not explain variance in 6MWD beyond past walking behaviour.
- Illness cognitions explained variance in objective walking ability beyond past walking behaviour, perceived behavioural control and walking intention.
- Taking into account past walking behaviour, attitude, subjective norm and perceived behavioural control regarding walking treatment, and perceived consequences, illness coherence, personal and treatment control, and risk factor attributions are psychosocial variables that should be targeted when developing and evaluating interventions to facilitate walking in people with IC.

Chapter 7. Feasibility of a randomised controlled trial of a physiotherapist-led behaviour-change intervention targeting walking in people with IC

7.1 Introduction

Qualitative and quantitative evidence support the TPB and CSM as viable frameworks for an intervention to facilitate walking in people with IC (Chapters 5 and 6). To date, the TPB has not been applied in the development of walking interventions for people with IC; however, a pilot trial of a brief home-based intervention that was informed by the CSM, and which increased walking behaviour in people with IC, suggests that illness cognitions might be important targets for intervention (Cunningham et al., 2012; Cunningham et al., 2013). While these findings demonstrate a promising way forward for supporting walking behaviour change, only individuals newly diagnosed with IC and who were managed conservatively were included (Cunningham et al., 2013; Cunningham et al., 2012). Qualitative data highlight a need for interventions suitable for the wider population of people with IC (Chapter 5), and suggests that many individuals with IC, including those with longstanding symptoms (i.e., >2 years) or who had undergone revascularisation, are not achieving walking guidelines and desire further support to self-manage their IC.

Interventions that increase walking behaviour should also demonstrate improvements in clinical outcomes for IC, to determine whether behaviour has been changed sufficiently to improve health. A primary treatment aim of walking for IC is improved walking ability (Norgren et al., 2007); however, there is a dearth of research exploring the effectiveness of behaviour-change interventions to increase clinical outcomes for IC (Chapter 4), despite the availability of validated measures that are easy to administer, low-cost and acceptable to participants, such as the 6MWT (Montgomery and Gardner, 1998). Cunningham et al. (2013; 2012) reported increased daily walking behaviour, but did not measure objective walking ability, so conclusions cannot be drawn regarding the effectiveness of that intervention on health.

Alongside outcome (i.e., effectiveness) evaluation, there is a growing drive to evaluate and report processes underpinning the delivery and uptake of complex interventions, including treatment integrity (i.e., the extent to which an intervention has been delivered as intended by the protocol), causal mechanisms, and contextual factors, which could support implementation to practice (Craig et al., 2008; Moore et al., 2014). Previous studies did not detect a treatment effect on theory-based beliefs proposed as mechanisms of change (Cunningham et al., 2013; Cunningham et al., 2012). One explanation for this finding was the use of non-validated measures of walking treatment beliefs (e.g., walking personal control and walking consequences), which were framed by the authors within the CSM, but which are conceptually defined and operationalised within the TPB. Measures with demonstrated psychometric properties might better assess theory-based cognitive variables targeted by the intervention. Additionally, only pre-randomisation and follow-up assessment was carried out, and an interim post-intervention assessment would enable longitudinal evaluation of change in targeted variables and mediational analyses in a full-scale trial. Finally, data on treatment integrity might have supported the reliability and validity of results (Pereplechikova and Kazdin, 2005; Borrelli, 2011).

An important stage in intervention development and evaluation, in particular to understand processes underlying intervention effects and treatment outcomes, involves replication of the core components of the intervention (Michie et al., 2009). Therefore, the study evaluates core components (e.g., BCTs) of a previously reported intervention (Cunningham, 2010; Cunningham et al., 2012), while developing and refining the methods to address key limitations, including those described above, through feasibility testing.

Feasibility research enables evaluation of the likelihood that the intervention will be effective and whether it is worth continued testing (Bowen et al., 2009). In addition, it identifies where and how the protocol or intervention requires modification for a definitive trial, focusing on areas such as acceptability (e.g., by participants and stakeholders), adaptation (e.g.,

modifications to an intervention), and expansion (e.g., building on results of an effective intervention for delivery to a new population or setting) (Bowen et al., 2009).

An important adaptation of the intervention delivery in the current study explores the feasibility of intervention delivery by a physiotherapist. As specialists in exercise rehabilitation and prescription, physiotherapists have a central role in changing exercise and physical activity behaviour, such as walking for IC. According to the Health and Care Professions Council (2013), physiotherapists' scope of practice includes an understanding of psychosocial factors that influence health behaviour and responses to physiotherapy treatment. Physiotherapy enhanced by psychological behaviour-change interventions can increase patient self-efficacy and physical functioning (McGrane et al., 2015). However, interventions are frequently delivered by other healthcare professionals alongside physiotherapy, and physiotherapists express a desire to develop their delivery of psychological techniques (Alexanders et al., 2014). Therefore, the role of the physiotherapist in supporting increased walking among individuals with IC, employing psychological BCTs, needs further exploration.

7.1.1 Aims

This study aims to refine and evaluate the feasibility of an RCT comparing a brief physiotherapist-led behaviour-change intervention targeting walking to an attention-control among people with IC.

7.1.2 Objectives and feasibility criteria

Feasibility objectives of the study and criteria used to evaluate the objectives are indicated in Table 7.1.

Table 7.1 Study objectives and criteria used to evaluate the feasibility of an RCT of a physiotherapist-led home-based behaviour-change intervention targeting walking among individuals with IC

Feasibility objectives	Feasibility criteria
a) to evaluate study retention of participants	Study retention at 16 week follow-up will be at least 60% (n=14/24) based on retention rates of past trials of home-based walking interventions in individuals with IC (Al-Jundi et al., 2013; Galea et al., 2013)
b) to evaluate participant compliance with the treatment and attention-control protocols	At least 60% (n=14/24) of participants will complete all treatment and attention-control sessions
c) to evaluate the suitability of the proposed outcome measures of objective walking ability, walking behaviour and theory-based constructs	Missing data at each time point will be less than 10% for each outcome, based on evidence that this is the threshold below which data missing at random will not be affected by the choice of treatment (Roth, 1994)
d) to explore the variability of proposed objective walking outcomes in order to estimate the treatment effect	Sufficient data will be collected to estimate the effect size (Hedges, 1981) of the treatment on 6MWD and walking behaviour compared with the attention-control, and to explore the precision of measurement across a range of CIs
e) to explore the suitability of proposed methods for evaluating treatment integrity	A consensus score using the Motivational Interviewing Treatment Integrity (MITI) across audio-recorded segments of the treatment sessions will be achieved by two raters

7.2 Methods

7.2.1 Study design

An acceptance and feasibility study of a two-arm single-blinded RCT was conducted.

7.2.2 Ethical approval

Ethical approval was obtained on 18 February 2013 from NRES Committee North West – Greater Manchester West (reference 14/NW/0089) (Appendix 1). Approval from the Departments of Research and Development, Guy's & St Thomas' NHS Foundation Trust was confirmed on 2 April 2014 and from King's College Hospital NHS Foundation Trust on 15 July

2014 (CSP reference 143466). The trial is registered on the ISRCTN database (ISRCTN55465549).

7.2.3 Development of treatment and attention-control scripts

Materials (Appendix 6) for the behaviour-change intervention targeting walking (treatment) were adapted from previous research (Cunningham, 2010). The intervention was expanded based on findings of Chapters 4 and 5, and refined following consultation with individuals with PAD and healthcare professionals.

Incorporating the views of individuals with PAD

A purposive sample of eight participants (n=6 male, n=3 classic IC, mean age 69.8 years, [range 56–82], mean 6MWD 338.43 metres [range 237.11–466.20]) in the cross-sectional study (Chapter 6) was invited to comment on the intervention structure and material. Participants felt that home and telephone delivery was convenient, although they would also be willing to attend clinic. Medical terms (e.g., atherosclerosis) and illustrations (e.g., image of vascular tree) presented in the intervention script required clarification. Some participants felt the content was helpful, although familiar, and so could be expanded to provide more depth and tailored information. Overall, participants felt the intervention was acceptable and relevant (Appendix 6).

Incorporating the views of healthcare professionals

A health psychologist and two physiotherapists were invited to comment on the intervention structure and material. To comply with the CSM and a patient-centred approach, aspects of the intervention script which implied a cognitive or emotional response were modified in order to elicit participants' illness representation (e.g., the text "You may worry that walking will harm your legs..." was replaced with a prompt to elicit the impact of IC on the individual and reassurance that walking does not cause harm). Treatment experiences and appraisals were elicited in order to elicit participants' attitude, subjective norm and perceived resources and barriers to engaging in walking. A discussion about walking was framed within the context of

their wider treatment history, to support the resonance among individuals with longstanding PAD and who had considered or undergone revascularisation. A walking prescription was framed within the recommendations for IC and tailored to individuals' current walking behaviour. Finally, aspects of the script, and particularly the booster telephone sessions, were developed to provide more structure and detail with suggestions on how to manage resistance to change, and support patients who are both successful and unsuccessful in carrying out their action plans and achieving behavioural goals.

Incorporating the findings of qualitative and cross-sectional data

Key adaptations to the intervention based on findings from Chapters 4 and 5 sought to a) elicit participants understanding and previous experiences of treatment for IC in order to frame walking in a relevant context; and b) provide explicit information on the realistic outcomes of walking for IC; and c) include explicit instruction on the established guidelines recommending walking. For example, participants were invited to discuss any previous treatment they had for their IC (Session 1). If walking therapy was not reported, then participants were asked if they had heard about walking exercise as a treatment for IC, what current walking activity they were engaged in, and what their experiences were of walking. Specific and general benefits of walking were provided. Specific benefits of walking including potential improvements in the distances walked before pain onset or before needing to stop and rest. General benefits of walking included a greater ability to engage in important daily activities, and greater maintenance or recuperation of health and mobility if undergoing revascularisation. Participants were informed of guidelines for IC to walk for at least 30 minutes on at least 3 days/week (Session 1). "Walking through pain" was defined as walking to moderate pain intensity before stopping to rest, and then continuing on once pain subsided, although some people with IC are able to carry on walking without stopping as their pain may not reach a moderate level. Walking intensity was further defined as walking at a brisk pace that brings on pain within the first 3-5 minutes of walking. Participant were encouraged to think about the guidelines, and how much walking they were currently doing, and set a plan to progress toward achieving the guidelines (Session 2).

Table 7.2. Summary of key adaptations to develop a physiotherapist-led home-based behaviour-change intervention targeting walking among individuals with IC

	Cunningham (2010)	Extended intervention
Theoretical underpinning	<ul style="list-style-type: none"> • CSM 	<ul style="list-style-type: none"> • CSM and TPB
Target population	<ul style="list-style-type: none"> • Newly diagnosed IC 	<ul style="list-style-type: none"> • All individuals with stable IC (including longstanding PAD and previous revascularisation).
Provider	<ul style="list-style-type: none"> • Researcher 	<ul style="list-style-type: none"> • Agenda for Change Band 6 Physiotherapist
Mode and duration of contact	<ul style="list-style-type: none"> • 2 x 60 min face-to-face consultation in participant homes and 2 x 20 min booster telephone calls 	<ul style="list-style-type: none"> • 2 x 60 min face-to-face consultation in participant homes and 2 x 20 min booster telephone calls
Intervention content		
Session 1		
Opening	<ul style="list-style-type: none"> • Elicit understanding of IC 	<ul style="list-style-type: none"> • Elicit understanding of IC and impact on value-based activities
Introduction on IC	<ul style="list-style-type: none"> • Provide information on the cause of IC (i.e., narrowed arteries and lack of oxygenated blood flow) • Present illustrations of the vascular tree and a narrowed artery 	<ul style="list-style-type: none"> • Provide information on the cause of IC • Assure patient that pain is not a sign of damage or harm • Present simplified illustrations of the vascular tree and narrowed artery
Risk factors for IC	<ul style="list-style-type: none"> • Provide information on risk factors (e.g., cholesterol, smoking, blood pressure, physical activity, obesity, diabetes) 	<ul style="list-style-type: none"> • Elicit perceived cause of IC • Provide information on risk factors and review those relevant to participant's current management
Treatment for IC	<ul style="list-style-type: none"> • Provide information on benefits of walking, including a) pain-free walking ability; b) change in blood flow to lower-limb; c) stimulated collateral blood flow; d) reduced systemic atherosclerotic build-up. 	<ul style="list-style-type: none"> • Elicit previous treatment experiences and appraisal of treatment • Provide information on benefits of walking including a) pain-free walking ability, b) maximal walking ability; c) ability to resume daily activities; d) efficacy of walking compared with invasive treatments; e) general health and mobility. • Provide information on mechanisms of walking benefits including a) oxygen extraction by skeletal muscle; b) collateral blood flow; c) changes in gait; d) reduced inflammation.
Walking advice	<ul style="list-style-type: none"> • Must be done regularly and consistently to ensure benefits are not lost 	<ul style="list-style-type: none"> • Elicit current walking regime and experiences • Provide recommendations of 30 minutes walking on ≥ 3 days/week, at a "brisk pace" that elicits pain within 3-5 minutes, and "walking through pain."

Preparing for change	<ul style="list-style-type: none"> •Elicit experiences of current walking and benefits of walking more •Utilise 0-10 rating to elicit motivation and confidence to change walking behaviour •Elicit personal strengths and social networks which may support success 	<ul style="list-style-type: none"> •Elicit experiences of current walking and benefits of walking more •Utilise 0-10 rating to elicit motivation and confidence to change walking behaviour •Assure participant that walking may progress at an individual rate toward achieving recommendations
Session 2		
Opening	<ul style="list-style-type: none"> •Brief review of key topics discussed in previous session 	<ul style="list-style-type: none"> •Brief review of key topics discussed in previous session
Goal setting and action planning	<ul style="list-style-type: none"> •Elicit individual goals and value-basis •Use worksheet to record walking goal •Record what, when, where and with whom the individual will engage in planned walking •List up to 3 barriers to achieving goal and problem solve •Record milestones for participant to establish that plan is working 	<ul style="list-style-type: none"> •Elicit individual goals and value-basis •Use worksheet to record walking goal •Record what, when, where and with whom the individual will engage in planned walking •List up to 3 barriers to achieving goal and problem solve •Record a strategy to monitor goal achievement
Telephone booster sessions	<ul style="list-style-type: none"> •Elicit participant attempts at achieving walking goal •Identify barriers and strategies to overcome these 	<ul style="list-style-type: none"> •Elicit and reinforce participant attempts at achieving walking goal •Discuss and revise goals, barriers and problem solving if necessary

CSM, Common Sense Model of Illness Representations; TPB, Theory of Planned Behaviour.

Treatment

Treatment included two 60 minute individual face-to-face sessions held approximately 1 week apart at participants' homes, and two 20 minute booster telephone calls at 6 and 12 weeks.

Session 1 was designed to elicit and modify maladaptive illness and treatment beliefs, and was supported by illustrations of the lower-limb vascular tree and of an occluded blood vessel.

Session 2 aimed to establish behavioural and outcome goals, to agree an action plan, and to problem solve anticipated barriers with the participant. A work sheet was used to record goals and planning, and a copy was provided to participants. The booster telephone call was designed to prompt a review of goals and provide feedback on performance. Motivational interviewing (social support) was employed as a BCT and as a vehicle for delivering other BCTs across all sessions. Targeted BCTs were employed across the sessions as previously defined (Cunningham, 2010), and updated to reflect the latest Behaviour Change Taxonomy (version 1)

(Michie et al., 2013) (Table 7.3). Complete scripts and materials used during each session are provided in Appendix 6.

Attention-control

The attention-control was developed to mirror the treatment intervention, but targeted dietary behaviour rather than walking. Treatment scripts were maintained, with the exception that any content promoting walking exercise was replaced by content that promoted public health dietary behaviour, which was sourced from a British Heart Foundation (2013) manual (Appendix 6).

Readability of scripts

Treatment and attention-control scripts were compared for readability, and respective scores for Flesch reading ease were 61.0 and 70.8, and for Flesch-Kincaid grade level were 8.5 and 7.2. These values indicate that scripts were similar and met standards appropriate for general readability.

7.2.4 Physiotherapist training

An Agenda For Change Band 6 physiotherapist was recruited to deliver the intervention and attention control. The physiotherapist was familiarised with the intervention scripts and materials, and attended 1 day (7.5 hours) of training in motivational interviewing through a course accredited by the British Psychological Society. Subsequently, five mock sessions with feedback, lasting approximately 60–90 minutes were provided with the chief investigator (LMB, an academic physiotherapist; 2 sessions), the co-investigator (JAW, an academic and clinical psychologist; 1 session), and the researcher (MGH; 2 sessions). The total duration of formal training was approximately 15 hours. In addition, ongoing supervision and feedback was provided (LMB) based on audio-recorded sessions with participants.

Table 7.3 BCTs included in a physiotherapist-led home-based behaviour-change intervention targeting walking among individuals with IC

Session	BCT	Definition	Delivery of BCT
Throughout all sessions	Social support (general)	Advise on, arrange, or provide social support, or non-contingent praise or reward for performance of the behaviour, and encouragement and counselling when directed at the behaviour (e.g., motivational interviewing)	Physiotherapist trained in motivational interviewing, values-based goals elicited to support autonomy, change talk facilitated through patient-centred dialogue
Session 1	Information about health consequences	Provide information about health consequences of performing the behaviour	Potential benefits of walking discussed, including ability to walk further before pain onset or need to stop and rest.
Session 2	Goal setting (behaviour)	Set or agree on a goal defined in terms of the behaviour to be achieved	Walking goal defined in terms of frequency, duration, intensity, and context in based on current activity with the aim of progressing toward recommended walking level
	Goal setting (outcome)	Set or agree on a goal defined in terms of a positive outcome of wanted behaviour	Value-based goal identified which would be facilitated by improved walking ability (e.g., work, hobby, social activity)
	Problem solving	Analyse or prompt analysis of factors influencing the behaviour and generate or select strategies that include overcoming barriers and / or increasing facilitators	Participants encouraged to identify up to three barriers which may prevent them achieving their goal, and realistic solutions discussed and agreed
	Action planning	Prompt detailed planning of behaviour performance, including at least one of: context, frequency, duration, or intensity	Action plan worksheet completed, recording details of the context, frequency, duration and intensity of walking goal
	Self-monitoring of behaviour	Establish a method for the person to monitor or record their behaviour as part of a behaviour-change strategy	Physiotherapist discussed methods to monitor daily walking (e.g., wearing a watch, or using landmarks to note distance achieved)
Booster telephone calls	Review behavioural goals	Review behavioural goals jointly and consider modifying goal or behaviour-change strategy in light of achievement	Walking behaviour discussed relative to goals and revised as appropriate to be more achievable or challenging
	Review outcome goals	Review outcome goals jointly and consider modifying goals in light of achievement	Value-based goal considered relative to behaviour change revised if no longer salient
	Feedback on behaviour	Monitor and provide informative or evaluative feedback on performance of the behaviour	Reported walking discussed in light of individual goals are recommended walking treatment for IC

Behaviour-change techniques (BCTs) are defined according to the Behaviour Change Taxonomy (version 1) (Michie et al., 2013).

7.2.5 Eligibility criteria

Participants met the following inclusion criteria:

- 1) adults aged ≥ 18 years; and
- 2) IC diagnosed by a vascular clinician, and based on results of established methods (e.g., ABPI, duplex ultrasound, computed tomography, magnetic resonance imaging) against recommended criteria (Norgren et al., 2007), and confirmed by response to the SDCQ.

Exclusion criteria were:

- 1) asymptomatic PAD or rest pain established by the SDCQ;
- 2) revascularisation (e.g., endovascular treatment or bypass surgery) scheduled in the upcoming 4 months because this could influence walking treatment and illness cognitions, and preclude individuals from engaging in walking;
- 3) the presence of a comorbidity other than IC (e.g., knee osteoarthritis, back pain) self-reported as the primary limitation of walking because this could influence walking treatment and illness cognitions, and walking outcomes;
- 4) the presence of a condition for which it is unadvisable to increase walking (e.g., unstable angina) as this could compromise participant safety or influence walking treatment and illness cognitions; and/or
- 5) inability or refusal to provide informed consent.

7.2.6 Sampling and recruitment

Individuals from Guy's & St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust, identified in vascular outpatient clinics, and who completed the cross-sectional observational study (Chapter 6) and consented to being contacted for future research, were informed of the study by post. A convenience sample of 24 participants was recruited, based on recommendations for the minimum sample size of 12 per group for pilot studies required to ensure feasibility and precision of estimates of variance (Julious, 2005). Information letters were sent to all 94 individuals by post. After at least 1 week, the researcher

contacted participants by telephone and invited those who were interested to be screened for eligibility.

7.2.7 Outcome measures

Descriptive variables

Sociodemographic and clinical characteristics. The following sociodemographic variables and clinical characteristics were assessed by self-report at baseline: age, gender, ethnicity (White, mixed/multiple ethnic background, Asian/Asian British, Black/African/Caribbean/Black British, or other), smoking status (current, currently quitting or cutting down, previous, or never), presence of comorbidities (diabetes mellitus, cholesterol, hypertension, cardiovascular disease, renal disease, previous heart attack, or stroke), current medication for IC (yes/no), duration of symptoms (<1 year, 1–2 years, >2 years), other mobility-limiting symptoms or conditions (yes/no), self-reported advice to walk, and participation in supervised exercise therapy within the past 3 years (yes/no) (Appendix 6).

Physical and psychological outcomes. Walking, theory-based constructs, and descriptive clinical variables were assessed and are described in full in Chapter 3 (Table 7.4).

Table 7.4 Outcome measures included in a feasibility study of an RCT evaluating a physiotherapist-led home-based behaviour-change intervention targeting walking among individuals with IC

Variable	Measure
Objective walking ability	
6 Minute Walk Distance (6MWD)	6 Minute Walk Test (6MWT)
Pain-Free Walking Ability (PFWA)	6MWT
Maximal Walking Ability (MWA)	6MWT
Walking behaviour	
Objective walking behaviour	Pedometer step count
Self-reported walking behaviour	Baltimore Activity Scale for Intermittent Claudication (BASIC)
Theory-based constructs	
Walking treatment cognitions	Theory of Planned Behaviour Questionnaire (TPB)
Illness cognitions	Revised Illness Perception Questionnaire (IPQ-R)
Barrier self-efficacy	Barrier Self-Efficacy Scale for Intermittent Claudication (BSES)

Action Planning	Action Planning Questionnaire
Action Control	Action Control Questionnaire
Descriptive clinical variables	
Lower-limb symptom classification	San Diego Claudication Questionnaire (SDCQ)
Health-related quality of life	Medical Outcomes Survey Short Form-12 version 2 (SF-12v2)
Perceived activity intensity	Borg Rating of Perceived Exertion (RPE)
Perceived pain intensity	Borg Category–Ratio 10 Scale for Pain (CR10)
Body mass index (BMI)	Standard scales

Treatment integrity. The Motivational Interviewing Treatment Integrity Code (MITI) is a behavioural coding tool designed to assess competence of delivery of motivational interviewing (Moyers et al., 2005). It was developed to provide a quick and simple rating for the purposes of evaluating treatment integrity or providing feedback to therapists. The MITI provides a Global Spirit Score across five dimensions: 1) evocation (extent to which the therapist elicits and expands the client’s motivation to change); 2) collaboration (extent to which the therapist engages the client as an equal, knowledgeable partner); 3) autonomy/support (extent to which the clinician supports and actively fosters the client’s perception of choice); 4) direction (the extent to which the clinician maintains focus on a targeted behaviour); and 5) empathy (extent to which the clinician understands or aims to grasp the client’s perspective and feeling). Each dimension is rated on a 5-point Likert scale, with the rater assuming a score of three and rating up or down from that neutral score.

Global Spirit Scores reflect a holistic evaluation of therapist competence: a score of 3.5 (range 0–5) demonstrates beginning proficiency, and competency is defined as a score of 4. The MITI demonstrates moderate inter-rater reliability (ICC 0.51–0.58) and was validated against the Motivational Interviewing Skills Code, which it was derived from, and which is a comprehensive tool that rates both therapist and client behaviour using full tapes over several

passages (Moyers et al., 2005). The MITI is widely applied because of its ease of use, and is suitable for novice raters, although psychometric properties are preliminary.

For each of the 12 participants in the treatment group, a 10 minute segment of audio recordings was randomly selected from Session 1 or Session 2 (Pierson et al., 2007). Two raters (MGH and PD [Trainee Health Psychologist]) evaluated a single pass of each segment assigning a Global Spirit Score for each dimension. Discrepancies between individual ratings were discussed until consensus was achieved.

7.2.8 Procedure

Baseline assessment. Participants attended a 1 hour appointment at the Division of Health and Social Care Research, King's College London (London, UK). Participants were asked if they had read the information letter and invited to ask any questions. Participants were asked to read, complete and sign three copies of the consent form, one which was filed in participants medical notes, one which was retained by the researcher, and one which was provided to the participant for their own reference. Questionnaires (sociodemographic and clinical characteristics, SF-12v2, BASIC, TPB, IPQ-R, BSES, Action Planning, and Action Control) were administered and BMI measures obtained. The Borg CR10 and RPE were administered and the 6MWT was initiated (Chapter 3). At the end of the 6MWT the Borg CR10 and RPE were re-administered. The participant was invited to rest, either seated or standing, for as long as they felt necessary. Stride length was estimated. The participant was then led back to the meeting room, seated, and provided instructions on the use of the pedometer and were asked to wear the device home and for the upcoming 6 days. They were provided with a letter reminding them of the 6 day period they had been asked to wear the pedometer.

Randomisation. Participants were randomised following baseline assessment to the treatment group or the attention-control group. Simple two-way randomisation was carried out by an unblinded researcher (LMB) using an online random number generator (www.randomizer.org). The randomised list was provided to the physiotherapist, who matched participants' study

identification, which was assigned at baseline assessment, to their allocated group prior to delivering Session 1. The researcher (MGH) administering baseline and follow-up assessments was blinded to participant allocation until study completion.

Intervention Session 1. At 1 week post baseline assessment, the physiotherapist delivered Session 1 of the treatment or attention-control. At the end of Session 1, the physiotherapist collected activity monitors and returned these to the researcher in an anonymised envelope.

Intervention Session 2. At 2 weeks post baseline assessment, the physiotherapist delivered Session 2 of the treatment or attention-control.

Post-intervention assessment. At the end of Session 2, the physiotherapist provided participants with a questionnaire pack and postage-paid envelope, and provided instructions to complete the questionnaires within 48 hours.

Booster telephone calls. At 6 and 12 weeks post baseline assessment, the physiotherapist delivered booster telephone calls to participants during a prearranged time and date.

Follow-up assessment. At 16 weeks post baseline assessment, participants attended a 1 hour follow-up appointment at the Division of Health and Social Care Research, King's College London (London, UK). Questionnaires were administered, then the 6MWT was conducted, with pre- and post-test administrations of the Borg CR10 and RPE. Participants were instructed on the use of the pedometer, and given a letter reminding them of the 6 day period they had been asked to wear the pedometer, and a pre-paid envelop for returning the device.

7.2.9 Analyses

Statistical analyses were carried out in SPSS Statistics Software version 21.0 (IBM Statistics Inc., Armonk, NY, USA). Statistical significance was set at $p < 0.05$.

Descriptive analyses

Sociodemographic and clinical characteristics are presented as means \pm SD or 95% CIs for continuous variables, and frequencies (%) for categorical variables.

Missing value analyses were completed to identify and describe patterns of item non-response by item, scale, and time of measure. The rate of missing data was defined as the proportion (percentage) of participants with incomplete data for a variable at a given assessment time point.

Distributions of outcome measures were explored for normality by visual inspection of histograms and normal Q–Q plots, and calculating standardised scores for skewness (z_s) and kurtosis (z_k) (Chapter 6) (Field, 2013). Absolute and percentage change scores for all outcome variables were computed.

Associations and effect estimates

The relationship between targeted cognitions (i.e., TPB, CSM, barrier self-efficacy, and self-regulatory processes) and walking outcomes (i.e., 6MWD and objective walking behaviour) were estimated by determining Spearman rank correlation coefficients (Tabachnick and Fidell, 2013), and defined as small ($r=0.10$), medium ($r=0.30$), and large ($r=0.50$) (Cohen, 1988).

Estimates of the magnitude of the effect and variance of the treatment on 6MWD and objective walking behaviour were determined by computing Hedges g (Hedges, 1981) and CIs for absolute (6MWD) and change (objective walking behaviour) scores. Hedges g was calculated using the square root of the pooled variance, with 0.20, 0.50, and 0.80 representing small, medium and large effects, respectively (Cohen, 1988). CIs for Hedges g were computed for probabilities of $\alpha=0.05$, 0.20, 0.30, 0.40, and 0.50. The corresponding critical values on a standardised curve are $z=1.96$, 1.28, 1.036, 0.841 and 0.674.

Inter-rater reliability for the MITI scale

Agreement between two raters applying the MITI was evaluated by calculating weighted kappa coefficients. Weightings applied to the 5 point categorical Global Spirit Scores were: 1 for equivalent ratings, 0.75 for ratings differing by 1 point, 0.5 for ratings differing by 2 points, and 0.25 for ratings differing by 3 or 4 points.

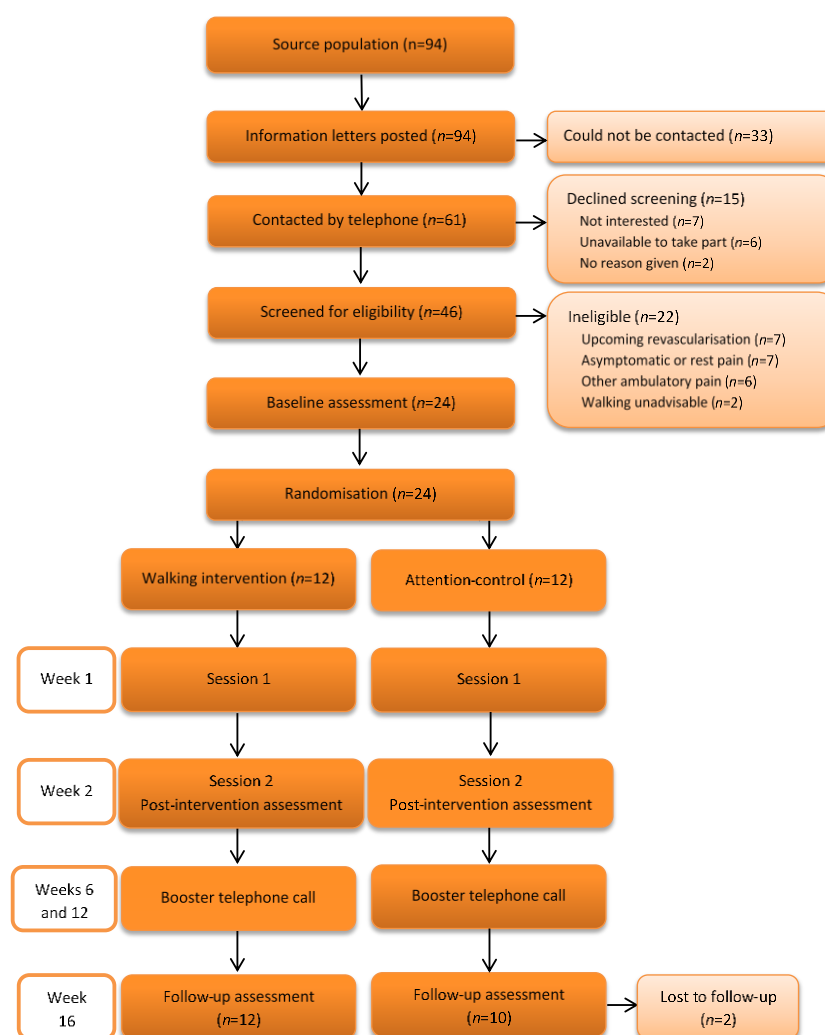
7.3 Results

7.3.1 Participant characteristics

Identification, screening and recruitment

Of the 94 participants who were sent information letters, 33 could not be contacted, 15 declined to be screened, and the remaining 46 were screened for eligibility. Among 46 participants screened for eligibility, 24 met the eligibility criteria and were enrolled onto the study. There was no substantial difference in age (mean 65.8 versus 67.4 years) or gender (24% of men and 33% of women enrolled) between individuals who were enrolled in the study and those who either declined or were ineligible. The complete flow of participants through the study is illustrated in Figure 7.1.

Figure 7.1 Flow of participants through a feasibility study of an RCT of a behaviour-change intervention targeting walking among individuals with IC



Baseline characteristics

There were no substantial differences between groups on key sociodemographic or clinical characteristics at baseline (Table 7.5).

Table 7.5 Baseline sociodemographic and clinical characteristics of participants in a feasibility study of an RCT evaluating a physiotherapist-led home-based behaviour-change intervention targeting walking among individuals with IC

Variable	Treatment, n (%)	Attention-control, n (%)
Age	66.3 ±8.8 ^a	67.1 ±11.2 ^a
Body mass index, kg/m ²	28.6 ±5.0 ^a	26.5 ±5.0 ^a
Male gender	9 (75.0)	10 (83.0)
Married	6 (50.0)	7 (58.3)
White ethnicity	11 (91.6)	9 (75.0)
Current smoker	4 (33.3)	6 (50.0)
Cardiovascular risk factors		
Diabetes	3 (25.0)	4 (33.3)
Hypertension	10 (83.3)	8 (66.7)
Dyslipidaemia	8 (66.7)	5 (38.5)
Cardiovascular disease	8 (66.7)	4 (33.3)
Renal disease	2 (16.6)	0
Past heart attack	4 (33.3)	4 (33.3)
Past stroke	0	3 (25.0)
Pharmacological management	2 (16.6)	1 (8.3)
Comorbid pain	3 (25.0)	3 (25.0)
Walking advice	6 (50.0)	7 (58.3)
Past supervised exercise therapy	5 (38.5)	3 (25.0)
Past revascularisation	1 (8.3)	2 (16.6)
BASIC, kcal/day	313.0 ±193.9 ^a	317.13 ±99.9 ^a
Lower-limb symptom classification		
Atypical IC	7 (58.3)	6 (50.0)
Classic IC	5 (38.5)	6 (50.0)
Duration of IC<1 year	1 (8.3)	0

n=24 (12 per group). ^aData are mean ±SD. BASIC, Baltimore Activity Scale for Intermittent Claudication; IC, intermittent claudication.

7.3.2 Descriptive results

Distribution of walking outcomes

Change scores for 6MWD and objective walking behaviour were approximately normally distributed for both the treatment (6MWD $z_s=-0.28$ and $z_k=-0.17$; objective walking behaviour $z_s=0.35$ and $z_k=-0.28$) and attention-control groups (6MWD $z_s=1.50$ and $z_k=1.28$; objective walking behaviour $z_s=0.40$ and $z_k=0.14$).

Walking change from baseline

Data for 6MWD and objective walking behaviour were available at baseline and 16 week follow-up for 22 and 13 participants, respectively (Section 7.3.3). Among participants in the treatment group, 6MWD decreased whereas objective walking behaviour increased. The opposite pattern was found in the attention-control (Table 7.6 and Section 7.3.3). At baseline, post-test scores for perceived pain intensity were similar between groups and corresponded with pain intensity that is “severe”, whereas perceived activity intensity was higher among attention-control participants (mean 14.2 \pm 2.10; “somewhat hard” to “hard [heavy]”) versus those in the treatment group (mean 11.5 \pm 4.0; “light”). By contrast, at follow-up there were no substantial differences between groups reflecting perceived pain (“severe”) or activity (“light” to “somewhat hard”) intensity following the 6MWT.

Table 7.6 Baseline, 16 week follow-up, and change scores for 6MWD and objective walking behaviour assessed during a feasibility study of an RCT evaluating a physiotherapist-led home-based behaviour-change intervention targeting walking among individuals with IC

Parameter	Treatment, mean \pm SD	Attention-control, mean \pm SD
6MWD		
Participants	12 ^a	10 ^a
Baseline, metres	390.44 \pm 101.81	378.05 \pm 157.06
Post-test perceived activity intensity	11.5 \pm 4.0	14.2 \pm 2.10
Post-test pain intensity	5.31 \pm 3.19	5.75 \pm 2.37
Follow-up, metres	381.92 \pm 113.51	387.93 \pm 161.84
Post-test perceived activity intensity	12.82 \pm 3.60	13.80 \pm 2.44
Post-test pain intensity	5.82 \pm 3.15	4.95 \pm 2.54
Change, metres	-8.52 \pm 42.29	9.88 \pm 42.15
Change, %	-4.23 \pm 12.56	1.01 \pm 13.346
Objective walking behaviour		
Participants	6 ^a	7 ^a
Baseline, steps/day	2247.02 \pm 1652.05	4343.28 \pm 3098.87
Follow-up, steps/day	3083.94 \pm 1882.59	4313.80 \pm 1113.45
Change, steps/day	836.91 \pm 625.83	-29.47 \pm 1471.43
Change, %	29.98 \pm 17.57	-2.41 \pm 40.81

^aData are the valid numbers of participants. 6MWD, 6 Minute Walk Distance.

Quality of life

The SF-12v2 mental component summary score increased from baseline in the treatment group (mean \pm SD change 2.76 \pm 3.56) and decreased in the attention control (mean \pm SD change -2.07 \pm 7.90). By contrast physical component summary score decreased from baseline in the treatment group (1.16 \pm 5.09) and increased in the attention-control (mean \pm SD change 6.7 \pm 7.0). Removal of one outlier in the attention-control reflecting physical component summary data still yielded a greater but less substantial change from baseline for this group (mean \pm SD change 4.87 \pm 4.17) compared with the treatment group.

Bivariate associations

Psychosocial outcomes were positive following treatment compared with baseline, with the exception of identity and cyclical timeline which were unchanged, and personal control which declined. By contrast patterns of change in psychosocial outcomes in the attention-control group were variable. The magnitudes of the associations between objective walking behaviour and 6MWD were $r=0.82$ and $r=0.59$ for the treatment and attention-control, respectively. Associations between psychosocial variables and walking outcomes were variable, and are illustrated in Table 7.7.

Table 7.7 Mean change from baseline in 6MWD and objective walking behaviour, and correlations with change scores of theoretical constructs assessed at baseline and 16 week follow-up in a feasibility study of an RCT evaluating a physiotherapist-led home-based behaviour-change intervention targeting walking among individuals with IC

Variable	Treatment group			Attention-control group		
	Change, mean (SD)	6MWD, <i>r</i> (n=7–12)	Objective walking behaviour, <i>r</i> (n=5–6)	Change, mean (SD)	6MWD, <i>r</i> (n=8–10)	Objective walking behaviour, <i>r</i> (n=5–7)
Attitude	1.50 (5.92)	0.52	0.60	-1.11 (5.23)	0.32	0.02
Subjective norm	0.33 (5.57)	0.15	0.60	3.11 (5.41)	0.33	-0.69
Perceived behavioural control	1.58 (6.05)	0.06	0.57	3.75 (7.17)	0.63	-0.33
Intention	0.83 (3.56)	0.11	0.71	2.33 (3.97)	-0.10	-0.75
Identity ^a	0.00 (1.91)	0.32	0.02	1.20 (2.44)	-0.31	-0.27
Acute timeline ^a	-0.83 (2.64)	0.02	0.01	-0.40 (3.34)	-0.19	0.45
Cyclical timeline ^a	0.00 (2.48)	-0.02	0.99	1.30 (2.16)	0.18	-0.74
Treatment control	1.16 (3.24)	0.05	0.80	-0.60 (2.99)	-0.33	-0.46
Personal control	-0.08 (2.35)	0.50	0.82	0.40 (5.17)	0.20	-0.10
Coherence	1.17 (3.10)	-0.07	0.56	-0.40 (3.20)	-0.24	0.24
Consequences ^a	-2.25 (3.22)	-0.12	0.27	-1.20 (1.69)	-0.72	0.06
Psychological attributions	-1.75 (3.33)	0.20	0.69	1.40 (4.25)	-0.08	0.14
Risk factor attributions	-0.67 (2.06)	0.48	0.40	0.33 (3.08)	-0.01	0.64
Immunity attributions ^a	-0.42 (1.51)	0.36	0.81	1.20 (1.35)	-0.12	-0.06
Accident/chance attributions ^a	0.33 (0.78)	0.21	0.01	0.10 (1.20)	-0.21	0.32
Emotion ^a	-1.17 (2.25)	0.02	-0.08	1.50 (4.99)	0.49	-0.35
Action planning ^b	13.56 (2.55)	-0.22	0.16	11.7 (4.29)	0.28	0.44
Action control ^b	19.00 (2.44)	0.31	NA ^c	16.7 (4.64)	0.14	0.87
Barrier self-efficacy	2.00 (8.27)	0.71	0.94	7.70 (18.02)	0.47	-0.10

Valid data (casewise) reflecting associations with 6MWD were available for n=7–12 (treatment) and n=8–10 (attention-control). Valid data (casewise) reflecting associations with objective walking behaviour were available for n=5–6 (treatment) and n=5–7 (attention-control). ^aA decreased score denotes improvement.

^bAction planning and action control reflect absolute scores at post-intervention assessment. ^cDegrees of freedom insufficient to run the analysis (n=2).

7.3.3 Evaluation of feasibility criteria

Objective 1: Study retention at 16 week follow-up will be at least 60%

Study retention at 16 week follow-up was 92% (n=22/24), and therefore the first feasibility objective was achieved. All participants in the treatment group completed the study protocol. Two participants in the attention-control group were lost to 16 week follow-up. Attempts were made to contact both participants in order to determine why they had not completed the study. One participant was awaiting test results for cancer screening and reported that his attention had turned to this new health issue. The second participant rescheduled his follow-up appointment twice, but did not attend; no reason was given. Participants lost to follow-up were younger than those who completed the study (mean \pm SD 57.0 \pm 2.8 years versus 67.6 \pm 9.8 years, respectively), and were both male. They did not otherwise differ on sociodemographic variables, clinical characteristics, or baseline outcome measures.

Objective 2: At least 60% of participants will complete all treatment and attention-control sessions

In total, 71% (n=17/24) of participants completed all prescribed sessions, therefore the second feasibility objective was achieved. Among the treatment and attention-control groups, 67% (8/12) and 90% (n=9/10) of participants, respectively, adhered in full. All participants completed Sessions 1 and 2 delivered via home visits. However, 4 participants in the treatment group and 2 participants in the attention-control group missed one booster telephone call; the second booster call was missed in 5 of 6 cases.

Objective 3: Missing data at each time point will be less than 10% for each outcome

Rates of missing data at baseline, post-intervention assessment (week 2), and follow-up assessment (week 16) were 4–36%, 18–32%, and <5%, respectively (Appendix 6). Item non-response was <5% for all self-reported variables for surveys returned at each time point.

Baseline. At baseline, missing survey data was <10% across outcome variables. Two participants (9%) had incomplete survey data reflecting TPB and IPQ-R variables. One participant (attention-control group) was missing 11 items, including a complete page of the TPB questionnaire (4 items reflecting attitudes, 3 reflecting subjective norms, 2 reflecting

intention, and 1 reflecting perceived behavioural control) and 1 item on the IPQ-R (risk factor attributions). One participant (attention-control group) was missing 1 item on the TPB (perceived behavioural control). Eight participants (36%; 4 treatment and 4 attention-control) were missing objective walking behaviour data. Four participants were missing 1 data point, three were missing 2 data points, and one participant was missing 4 data points. One participant (treatment), who dropped and damaged the pedometer, was missing day 1 and 2 step counts. That participant was provided with a new pedometer and monitoring continued from day 3 to 6. Two participants (one treatment, one attention-control) were missing day 6 data because their pedometers were collected 1 day early due the physiotherapists' schedule requirements. 6MWD data were complete.

Post-intervention assessment. At the post-intervention assessment, 9/22 (41%) participants had a complete dataset. Four participants (18%; 2 treatment and 2 attention-control) did not return their surveys by post. One participant (treatment) was missing 21 items, including a page of data on the IPQ-R (20 items) and 1 item of the IPQ-R causal attributions scale. One participant (treatment group) was missing 7 items, including 6 items on the TPB questionnaire (1 page) and 1 item on the barrier self-efficacy scale. The remaining seven participants (4 treatment, 3 attention-control) were missing 3 or fewer items across the TPB and IPQ-R surveys.

Follow-up. At the 16 week time point, 19/22 (86%) participants had complete datasets. Item non-response was <5% across self-reported measures. One participant (treatment) was missing day 6 pedometer step count because he posted the pedometer one day early in advance of travel plans. Data on objective walking behaviour were missing in entirety for one participant at follow-up (attention-control), who returned his pedometer after the 21 day data storage window and, as a result, data could not be retrieved from the device. 6MWD data were complete.

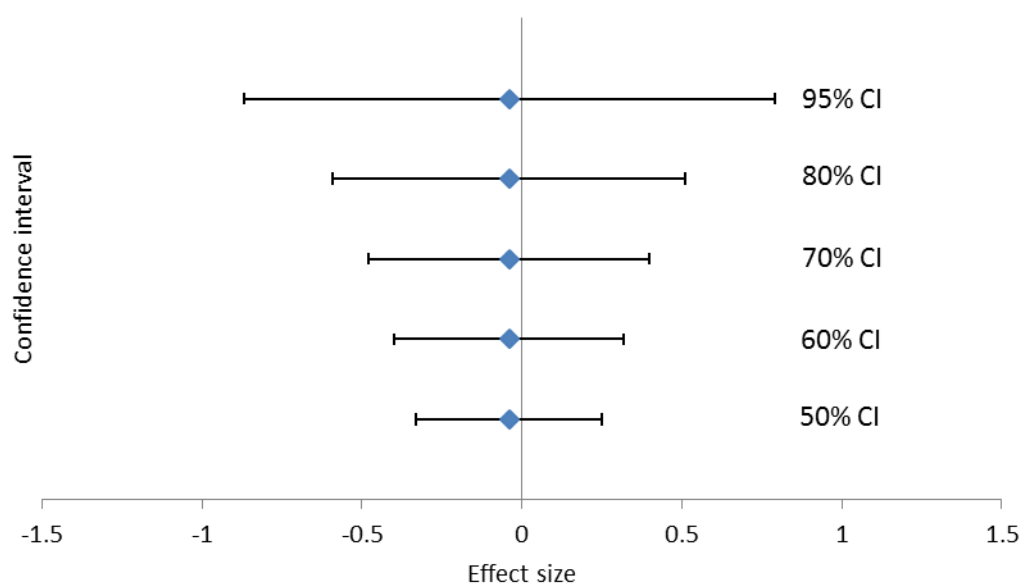
Objective 4: Sufficient data will be collected to estimate the effect size of the treatment on 6MWD and objective walking behaviour compared with the attention-control and to explore the precision of measurement across a range of CIs

6MWD and objective walking behaviour data presented as means and standard deviations for each time point are reported in Table 7.5. In the treatment and attention-control groups, 42% and 70% of participants had increased 6MWD, and 82% and 22% had increased their objective walking behaviour, respectively (Appendix 6).

Estimate of the effect: 6MWD

6MWD decreased among participants in the treatment group (median -6.67, IQR -31.05–17.71) and increased in the attention-control group (median 3.34, IQR -15.87–22.75). The estimated effect for scores at follow-up favoured the attention-control, Hedges $g=-0.04$ (95% CI -0.88, 0.79). The range of CIs suggest no true difference between groups (Figure 7.2).

Figure 7.2 Confidence intervals corresponding to the treatment effect on change in 6MWD compared with the attention-control



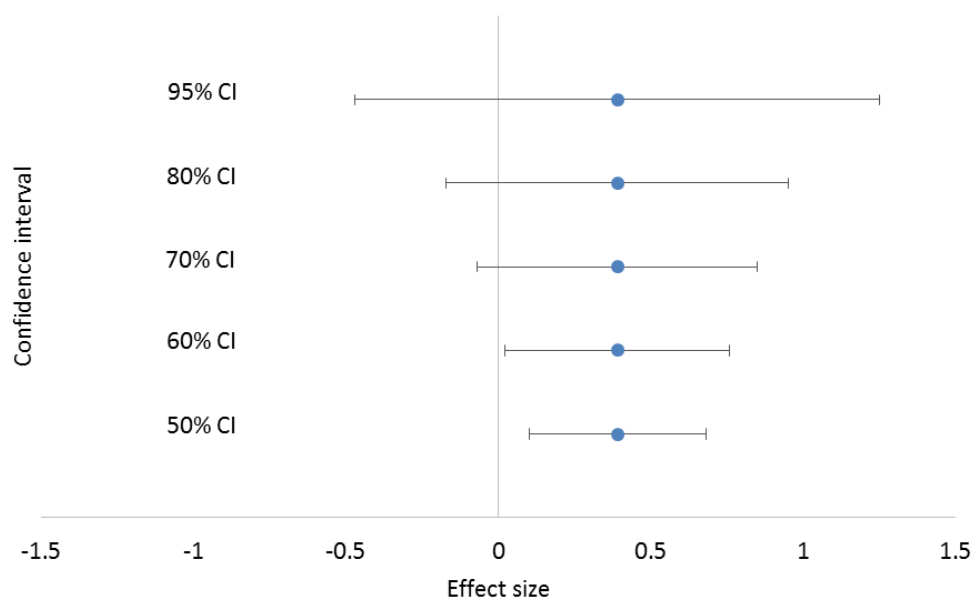
Sensitivity analysis accounting for missing data. A sensitivity analysis including participants lost to follow-up and assuming no change in 6MWD (i.e., last value brought forward) produced similar results (median -6.67 metres [IQR -31.05–17.68] change in 6MWD for the treatment versus median 1.85 metres [IQR -8.15–11.95] for the attention-control, Hedges $g=-0.08$ [95% CI -0.88, -0.72]).

Sensitivity analysis accounting for outliers. Three participants in the attention-control group were identified as outliers. Two participants had change scores falling above the IQR, whereas one had a change score falling below (Appendix 6). A sensitivity analysis was conducted with these participants removed. Change in 6MWD remained negative for the treatment (median -6.7 metres, IQR -31.1–17.7) and positive for the attention-control (median 3.1 metres, IQR -6.2–12.4). The treatment effect was reduced and negligible, Hedges g 0.00 (95% CI -0.93, 0.93).

Estimate of the effect: objective walking behaviour

Participants in the treatment group had a greater increase in objective walking behaviour (median 857.7 steps/day, IQR 282.6–1432.8) compared with those in the attention-control group (median 59.5 steps/day, IQR -942.4–1061.4). A small effect favouring the treatment group was detected, Hedges $g=0.39$ (95% CI -0.47, 1.25). The range of CIs provided evidence for a true difference between groups below a probability of $\alpha=0.40$ (Figure 7.3).

Figure 7.3 Confidence intervals for the effect of the treatment on objective walking behaviour compared with the attention-control



Sensitivity analysis evaluating 3 day pedometer data. A sensitivity analysis evaluated objective walking behaviour over 3 randomly selected days of pedometer data. Agreement between

mean 6 and 3 day walking behaviour was demonstrated for baseline (ICC 0.97, 95% CI 0.90, 0.99) and follow-up (ICC 0.91, 95% CI 0.76, 0.96) scores. Objective walking behaviour increased in the treatment group (median 492.33, IQR -256.18–1240.83), and decreased in the attention-control (median -269.66, IQR -2243.91–1704.59). A small effect favouring the treatment group was detected, Hedges $g=0.34$ (95% CI -0.36, 1.04).

Objective 5: A consensus score using the MITI across audio-recorded segments of the treatment sessions will be achieved by two raters

The MITI code was feasible and applicable to the brief 10 minute audio-recorded segments of the treatment sessions. Global Spirit Scores were achieved by each rater for all five dimensions after a single pass, and a final score agreed by consensus. The scale was appropriate and meaningful when applied to both Session 1 and Session 2 for the treatment group. Substantial inter-rater agreement was achieved overall for MITI scores ($\kappa=0.73$), and ranged across dimensions from $\kappa=0.71$ to $\kappa=0.76$ (Table 7.8) (Altman, 1991).

Table 7.8 Individual scores, consensus scores, and inter-rater agreement among two raters using the MITI code to evaluate audio-recorded treatment delivered by a physiotherapist in a home-based behaviour-change intervention targeting walking among individuals with IC

MITI dimension	Session 1						Session 2						κ
	01C	05C	06C	18C	21C	24C	03C	04C	08C	09C	14C	17C	
Evocation													0.74
Rater 1	2	1	4	2	3	4	4	3	3	2	4	4	
Rater 2	4	2	2	3	4	4	5	4	3	3	4	5	
Final score ^a	2	2	4	2	3	4	4	4	3	2	4	4	
Collaboration													0.71
Rater 1	1	1	4	2	3	4	5	3	3	3	4	5	
Rater 2	4	3	3	3	4	4	4	4	3	4	5	5	
Final score ^a	3	2	4	2	3	4	4	3	3	3	4	5	
Autonomy/ support													0.73
Rater 1	3	3	3	3	3	4	3	3	4	3	3	3	
Rater 2	3	4	4	3	4	3	4	4	3	3	4	5	
Final score ^a	3	3	4	3	3	4	3	3	4	3	3	4	
Direction													0.74
Rater 1	5	4	4	5	5	5	5	3	5	5	3	5	
Rater 2	5	3	3	5	5	3	4	5	5	4	4	5	
Final score ^a	5	3	4	5	4	5	4	4	5	5	4	5	
Empathy													0.76
Rater 1	2	3	3	2	3	3	3	3	3	4	4	5	
Rater 2	4	4	4	4	4	4	4	5	3	4	4	5	
Final score ^a	4	3	4	2	3	3	3	4	3	4	4	5	

n=12. ^aAchieved by consensus agreement.

7.4 Discussion

This study demonstrated the feasibility of a two-arm randomised trial comparing a behaviour-change intervention targeting walking to an attention-control among people with IC. This was the first study to target constructs from the TPB and CSM together to change objective walking behaviour and walking ability in this population, and the first to explore the effects of a theory-based intervention on objective measures of walking behaviour.

Objective walking behaviour increased following the walking intervention compared with the attention-control. The median 857.7 steps/day (IQR 282.6–1432.8) increase among participants in the treatment group corresponds with outcomes of other pedometer-based walking interventions (Tudor-Locke et al., 2011). Among older adults and individuals with long-term conditions, including PAD, 30 minutes of walking is approximately equivalent to 3000 steps assuming an average cadence of 100 steps/minute (Tudor-Locke et al., 2011; Montgomery and Gardner, 1998). Accordingly, participants in the treatment group increased walking behaviour by mean 8.6 minutes/day, or the equivalent of approximately 60 minutes/week.

By contrast, 6MWD decreased following treatment, and increased in the attention-control group. This might be explained by the magnitude of behaviour change described above, which was below the threshold for guidelines on frequency and duration of exercise for increasing walking ability in people with IC (i.e., 30 minutes on at least 3 days/week, or 90 minutes/week) (Norgren et al., 2007), so might not have been sufficient to garner an improvement in the clinical outcome (6MWD). In addition, walking intensity was not monitored, and it may be that participants were also not achieving this aspect of the walking guidelines. BCTs (Michie et al., 2013) that were not explicitly incorporated to the current intervention, but which might help address the challenge of achieving walking guidelines include the use of graded tasks (e.g., increasing the duration of walking by 5 minutes per session until 30 minutes is achieved), addressing discrepancies between current behaviour and goals, and providing feedback on the outcome of behaviour (e.g., explicit feedback on improvements in PFWA and MWA).

Study retention (92%) and treatment compliance (72% overall) were comparable with other home-based walking interventions for IC, which report study retention at 12 or 24 weeks ranging from 61–100% (Al-Jundi et al., 2013; Galea et al., 2013). In addition, the majority of intervention sessions and study assessments were completed within 1 week of the per-protocol timeframe. However, a high proportion of missing pedometer data reflecting objective walking behaviour at baseline assessment meant the feasibility criterion of <10% of missing data at each time point was not achieved, and should be addressed in a definitive trial.

Due to high within- and between-subjects variability in walking behaviour, estimates of missing pedometer data comes with a threat to validity. Among healthy adults, 3 day pedometer data demonstrates high agreement with 7 day pedometer data ($ICC > 0.85$) (Tudor-Locke et al., 2005), and, in people with IC, as little as 2 days of pedometer data provided a stable measure of walking behaviour (Sieminski et al., 1997). When 3 day pedometer data were analysed, 32% ($n=7$) of the sample data were recovered and results were consistent with 6 day pedometer data suggesting that feasibility of this method of data treatment. However, measures could also be taken to reduce the volume of missing data, for example by using text-based reminders (Sternfeld et al., 2012).

The proportion of missing pedometer data was lower and within the feasibility criteria at follow-up compared with baseline. It may be that participation in the study increased the saliency of wearing the pedometer, resulting in a greater likelihood of remembering or increased motivation to wear the pedometer. One potential source of participant motivation to wear their pedometer, which was not sealed, might have been to monitor walking. However, pedometer use was not coupled with explicit self-monitoring (e.g., logging steps in a diary), an important factor that increases the effect of pedometer use on behaviour (Bravata et al., 2007). Nevertheless, use of sealed pedometers would improve the validity of this outcome in future research, reducing the potential for a motivation enhancing effect. Alternately, there may be scope for employing pedometers as a low-cost motivational tool to increase self-directed walking behaviour in people with IC, although the best methods for

deploying this strategy in the context of the current home-based walking intervention would need to be explored.

7.4.1 Methodological considerations

This study has several strengths. The treatment intervention was based on previous research identified in a systematic review, and targeted psychosocial constructs and BCTs in order to increase walking. The intervention was developed with a strong theoretical underpinning, and evaluated theoretical constructs as process variables for change, addressing the lack of theory-driven walking interventions for IC (Chapter 4). Validated self-reported and objective measures of key variables, including psychosocial constructs and walking were included, and provide clinically meaningful outcomes for IC (e.g., 6MWD, PFWD, and MWD).

An attention-control comparison was an important strength of the methods used in this study. However, the fidelity assessment did not include an evaluation of treatment differentiation, that is, the extent to which the conditions differed from one another sufficiently to demonstrate manipulation of the independent variable as planned (Gearing et al., 2011), and may limit the interpretation of findings. The attention-control was modelled on content delivered during the walking intervention, incorporated explicit BCTs targeting dietary behaviour, and was delivered by the same clinician; therefore, evidence supporting treatment differentiation would exclude the possibility of contamination of the attention-control (e.g., by inclusion of BCTs targeting walking), or of transfer of learned cognitive or behavioural skills (Barnett and Ceci, 2002), and could therefore reduce the possibility of a type-II error. However, most research on transfer effects of health behaviours have focused on exercise as a gateway for dietary changes (Fleig et al., 2011; Fleig et al., 2014), and not the reverse.

Treatment integrity was reported for motivational interviewing, but not other BCTs delivered. The MITI was available as a validated tool for evaluating motivational interviewing, which was a key BCT underpinning treatment. However, measures of treatment integrity related to other BCTs have not been established, and require bespoke tools that are tailored to the

intervention. Future research should develop and employ appropriate measures of treatment integrity which could be used as part of a comprehensive process evaluation.

Self-reported postal data were not returned by five participants at post-intervention assessment, and contributed, alongside objective walking behaviour, to a high proportion of missing data. This problem could be overcome by allowing the option to administer surveys online, using text or telephone reminders prompting individuals to return surveys, or by obtaining missing responses from participants by proxy (e.g., telephone contact). A full-scale trial including a larger sample size would permit further exploration of patterns in missing data and require robust methods for missing data replacement, if necessary (Roth, 1994).

Recruitment rates could not be evaluated because participants were identified from the previous cross-sectional study (Chapter 6). However, recruitment to the cross-sectional study provides some indication of engagement for future studies. Current walking behaviour was not an inclusion criteria, and it is possible that, at baseline, some participants were already walking, or achieving walking guidelines potentially posing a ceiling effect on the magnitude of behaviour change. Self-reported (median BASIC total score 4.0, IQR 2.9–5.1) and objective (median step count 2522.3, IQR 1060.8–3983.8) data indicate, however, that baseline physical activity was low.

7.4.2 Conclusions

- A randomised trial comparing a brief home-based behaviour-change intervention targeting walking in people with IC to an attention-control, and delivered by a physiotherapist, is feasible.
- Criteria for feasibility were met and demonstrated study retention at 16 week follow-up, participant compliance to interventions, low rates of missing data for most outcomes, sufficient data to explore treatment effects on objective walking ability and behaviour, and suitability of the MITI as a method for evaluating treatment integrity.
- A definitive trial should incorporate methods for facilitating questionnaire and pedometer data collection to reduce the rates of missing data.

Chapter 8. Acceptability of a randomised controlled trial of a physiotherapist-led behaviour-change intervention targeting walking in people with IC: a nested qualitative study

8.1 Introduction

The feasibility of an RCT of a physiotherapist-led behaviour-change intervention targeting walking for IC was evaluated based on five criteria outlined in Chapter 7. An important aspect of the feasibility and piloting of novel interventions involves evaluating their acceptability to participants (Bowen et al., 2009; Craig et al., 2008). Understanding the acceptability of the study protocol and intervention components to individuals with IC could reveal factors underpinning study protocol and intervention adherence, processes of change, and intervention effects. In addition, the acceptability of a novel intervention to the physiotherapist involved in delivery provides important detail on the feasibility of training and potential implementation to practice.

Qualitative research is a useful approach to understanding processes underpinning an intervention and explaining findings, and provides an important means for user involvement and feedback in order to refine a study protocol and intervention components (Chapter 3). Therefore, a nested qualitative study was conducted to provide an in-depth evaluation of the acceptability of the study described in Chapter 7, from the perspective of participants and the physiotherapist.

8.1.1 Aims

This study aims to explore the experiences of individuals with IC and a physiotherapist who took part in a feasibility study of an RCT of a behaviour-change intervention targeting walking for IC (Chapter 7).

8.1.2 Objectives

The objectives of this study are:

- a) to evaluate the acceptability of the study protocol, treatment intervention, and attention-control intervention to participants with IC; and
- b) to support and explain findings of the feasibility study.

8.2 Methods

8.2.1 Study design

A qualitative study using semi-structured in-depth individual interviews and applying the Framework Method, and which was nested in a feasibility study of an RCT, was conducted

8.2.2 Ethical approval

Ethical approval was obtained on 18 February 2013 from NRES Committee North West – Greater Manchester West (reference 14/NW/0089) (Appendix 1). Approval from the Departments of Research and Development, Guy's & St Thomas' NHS Foundation Trust was confirmed on 2 April 2014 and from King's College Hospital NHS Foundation Trust on 15 July 2014 (CSP reference 143466).

8.2.3 Eligibility criteria

Inclusion and exclusion criteria are described in full in Chapter 7 (Section 7.2.5).

8.2.4 Sampling and recruitment

A purposive sample of 12 participants from the feasibility study (Chapter 7) and the physiotherapist were invited to an interview upon completing the study protocol. Sampling of participants was determined by an unblinded investigator (LMB) to reflect a range of participants based on the following ordered criteria: group allocation, ethnicity (White versus other), gender, past participation in an exercise programme, and median age of sample (<66 versus ≥66 years).

8.2.5 Outcome measures

Outcome measures are described in full in Chapter 7 (Section 7.2.7).

8.2.6 Topic guide development

Consistent with the Framework Method (Chapter 3), a topic guide (Table 8.1) was developed to reflect participants' experiences of the study protocol, the treatment or attention-control, therapeutic alliance with the physiotherapist, and targeted theoretical constructs. A second topic guide (Table 8.2) was developed for an interview with the physiotherapist and reflected experiences of training received, study management, delivery of the treatment or attention-control, understanding of theoretical processes underpinning the treatment, and therapeutic relationship with participants.

8.2.7 Procedure

Participants were invited to an audio-recorded interview lasting up to 45 minutes at the end of their follow-up assessment. The physiotherapist was invited to take part in an interview lasting up to 60 minutes following completion of the study. Interviews followed topic guides and were audio-recorded.

8.2.8 Analyses

Audio-recorded interviews were transcribed verbatim by one researcher (PD) and analysed using NVivo 9 (QSR International Ltd, Southport, UK). Key stages of the Framework Method were applied, including transcription, familiarisation, coding, development and application of the analytical framework, charting, and interpretation (Chapter 3) (Gale et al., 2013). Results were reviewed by two researchers (MGH and PD) and discussed in order to reach a consensus.

Table 8.1 Topic guide for participant interviews in a nested qualitative study evaluating the acceptability of an RCT of a physiotherapist-led behaviour-change intervention targeting walking for IC

Introduction

What I'd like to talk with you about are your experiences and views of taking part in this study, and the physiotherapist-led treatment you received for your leg pain.

Brief history

Before we begin to talk about the study and treatment, could you tell me a bit about the problem that you have with your legs from when it first started to your involvement in this study?

What have you tried over the years to improve your leg pain or discomfort?

- Has this helped at all?

Research experience

What were your thoughts when you heard about the research?

- Introduction letter
- Information sheet
- Organisation (location/timing of assessments)

Could there be any additional information that might have been helpful for you at that point?

How did you find this study (appointments at KCL)?

- Assessments
 - 6MWT – is this a suitable way to find out how you are doing?
- Pedometer – do you think this reflected your actual walking?
- Questionnaires – were these relevant, appropriate, meaningful?
- Travel and timing

Intervention experience

Can you tell me about your expectations before meeting the physiotherapist?

What has the treatment with the physiotherapist involved for you?

What was it like having physiotherapy consultations?

- Tell me about the home-based sessions?
 - Content (Session 1 versus Session 2)
 - Format (home versus clinic)
- Tell me about the follow-up phone calls?
- Dosage (number of sessions, duration, follow-up)

Do you have any suggestions for how this sort of treatment could be altered or adapted in the future?

- Timing – would intervention have been useful at another stage of your disease/diagnosis/treatment?

Outcomes and processes (illness and treatment beliefs)

How has this intervention affected you?

- Have you noticed any changes as a result of the treatment (physical)
- Apart from physical changes, how do you feel in yourself since the treatment (emotion)
- How do you see your leg problem now compared to before the physiotherapy? (cognitive/illness perceptions)
 - Do you see your diagnosis / condition differently than before?
 - Has it affected your understanding of your condition?
 - Has it affected your treatment options?

Therapeutic relationship

Can you tell me about the relationship you had with the physiotherapist?

Was this relationship similar or different compared to your relationship with other healthcare professionals you have seen about your leg pain?

Do you think a physiotherapist was the right sort of person to deliver an intervention like this?

Acceptability

Would you recommend this sort of treatment to other people with leg pain?

- What reasons do you think other people might have for not wanting or taking this sort of treatment for their leg pain?

Closing

Is there anything else you would like to tell me or you think I should know?

Table 8.2 Topic guide for a physiotherapist interview evaluating the feasibility and acceptability of an RCT of a home-based behaviour-change intervention targeting walking for IC

Introduction

What I'd like to talk with you about are your experiences and views about the training you received as part of this study, and of delivering the treatment intervention and attention-control intervention.

Brief history

Before we begin can you tell me a bit about your background (training and experiences) as a physiotherapist?

- Have you worked with people who have IC before? With CVD patients?
- Can you tell me about your experiences in research?

Training experience

Tell me about the training you received as part of this intervention (quality, adequacy, appropriateness to the task)

- Background reading on the subject
- MI Course (Motivational Interviewing and Beyond, Skills Development Centre)
- Volume and quality of mock sessions/feedback on mock sessions
- Feedback on ongoing fidelity checks of audio recorded treatment sessions
- What did you feel about the areas of learning addressed?
- Too little/too much?
- Has the training experience changed your practice?
- If so, how?

Study Management

Can you provide any feedback on the day-to-day management of the study?

- Quality and organisation of materials provided to support day-to-day management (e.g., study log, checklists, use of calendar)
- How might the study management or materials be altered/refined?
- Tell me about the balance of support you had versus autonomy given in managing your work related to this study?

Intervention delivery

Tell me about your experiences delivering the treatment intervention (i.e., the walking intervention?)

- What were the barriers and facilitators to delivering this intervention
- Focus on aspects of Session 1, Session 2, Booster call
- (Personnel) What band therapist/healthcare professional do you feel should be delivering this intervention?
- Competencies

-
- (Location) What are your thoughts on delivering home-based intervention?

Attention control

Tell me about your experiences delivering the intervention to the attention control group

- What were the barriers and facilitators to delivering this intervention?
- Did you feel comfortable, knowledgeable?
- Anything that helped during delivery or that might have been used to improve delivery?
- Any reactions/responses from patients?

Theoretical processes

Do you understand the theoretical processes behind this intervention?

- Yes – what helped
- No – what more would you like to know?

Is there anything else you would like to add about the delivery of the intervention?

Intervention Format

What do you feel about the intervention format?

Do you have any suggestions for how this sort of treatment could be refined/altered in the future?

- Timing of sessions/booster
- Volume and duration of sessions/booster
- Mode of delivery (face-to-face vs online etc.)
- Home based versus clinic-based
- Individual versus group based
- Physio- versus other-led

Therapeutic relationship

Can you tell me about building rapport/the relationship you had with the participants?

Can you tell me about any good relationships or experiences/challenging relationships or experiences

Closing

Is there anything else you would like to tell me or you think I should know?

8.3 Results

8.3.1 Participant characteristics

Sociodemographic and clinical characteristics of 12 participants (n=6 treatment, 6 attention-control) are listed in Table 8.3.

Table 8.3 Sociodemographic and clinical characteristics of participants in a nested qualitative study of the acceptability of an RCT evaluating a physiotherapist-led home-based behaviour-change intervention targeting walking in people with IC

Variable	Value, n (%)
Age	68.0 ±10.3 ^a
Body mass index, kg/m ²	26.6 ±4.0 ^a
Male gender	7 (58.3)
Married	5 (41.7)
White ethnicity	10 (83.3)
Current smoker	2 (16.7)
Cardiovascular risk factors	
Diabetes mellitus	2 (15.7)
Hypertension	8 (66.7)
Dyslipidaemia	5 (41.7)
Cardiovascular disease	7 (58.3)
Renal disease	1 (8.3)
Past heart attack	3 (25.0)
Past stroke	0
Comorbid pain	3 (25.0)
Treatment history	
Pharmacological management of IC	1 (8.3)
Walking advice	6 (50.0)
Past supervised exercise therapy	3 (25.0)
Past revascularisation	0
Self-reported walking behaviour, kcal/day ^b	126.5 ±18.9 ^a
Lower-limb symptom classification ^c	
Classic IC	5 (41.7)
Atypical IC	7 (58.3)
Duration of IC<1 year	1 (8.3)

n=12. ^aData are mean ±SD. ^bAssessed by the Baltimore Activity Scale for Intermittent Claudication. ^cAssessed by the San Diego Claudication Questionnaire. IC, intermittent claudication.

8.3.2 Descriptive and explanatory themes

Narrative accounts by participants and the physiotherapist demonstrated the acceptability of the trial and treatment protocol, and included suggestions to improve the programme in future. Themes are summarised in Table 8.4.

Table 8.4 Summary of themes illustrating participant and/or clinician experiences and the acceptability of an RCT evaluating a physiotherapist-led home-based behaviour-change intervention targeting walking in people with IC

Theme	Description
Acceptability of the research process and protocol	Participant experiences of assessments and appointments, and suggestions for improving the study conduct
Acceptability of the treatment and attention-control interventions	Format and content of the interventions, including mode of delivery, information provision, and materials
Perceived expectations and outcomes of the treatment and attention-control interventions	Participant expectations prior to the study commencing, and outcomes including cognitions, behaviour-change, and walking ability
Physiotherapist role as a person and professional	Participant expectations of physiotherapy, individual qualities, professional expertise, consistency and relationship building

Acceptability of the research process and protocol

Most participants felt they had received enough information prior to joining the study, but had little or no expectations of the research for them. One participant expressed initial uncertainty, which was relieved with more information, and following the baseline visit:

“It was a bit new at the time, but gradually getting into it provided more information, like an interview; you’re going to a new place or something and you’re not sure what is coming to you, and then suddenly you find out.” (13C, female, 55 years, attention-control group)

Despite uncertainties or unclear expectations, individuals reported positive experiences after taking part:

"I had only expected that you would study me, and hoped that would help other people a little bit. But it has had a positive result for me in that I'm actually doing more than I was." (04C, male, 59 years, treatment group)

Positive experiences included aspects of the research process, including walking and questionnaire assessments, which were relevant and appropriate based on participant accounts. For example, although participants were not informed of their performance during the 6MWT, some individuals viewed this as an opportunity to consider, or evaluate, their walking:

"[The 6MWT] gave me knowledge of how far I could go. When I'm out [walking], I'm not stopping to think that I'm really falling behind." (05C, female, 59 years, treatment group)

Others did not enjoy the 6MWT particularly, but appreciated that it was appropriate in the circumstances of the research:

"It's not something I enjoyed, but neither do I dislike it. It's just part of the test, if you like, and it's a function that needs to be done, and it's fine." (04C, male, 59 years, treatment group)

However, one individual suggested the 6MWT was not sufficiently challenging to elicit symptoms:

"It's slightly unrealistic because it's flat... so the impact on the legs was fairly marginal." (02C, male, 75 years, attention-control group).

Most participants viewed the pedometer as comfortable to wear (13C) and non-intrusive (02C), and reported not noticing it while it was worn. One individual in the treatment group, and one in the attention control, reported using the pedometer as a self-monitoring or motivational tool:

"I found it really helpful, almost to the extent to which I wish I had one. It really did encourage you on days when I looked at it and saw that I had done nothing...[and thought] 'Oh, wow, I've got to go, got to do some walking'." (04C, male, 59 years, treatment group)

"If you show me, every day, how many miles or how many steps I have to do, then I think it could give me a bit more confidence that at least I am achieving that goal." (13C, female, 55 years, attention-control group)

Participants were equivocal regarding questionnaire completion, but acknowledged the need for questionnaires as an assessment tool:

"Questionnaires are questionnaires, to be frank. They don't do anything for me. They're just a necessary part of your process and I'm happy to fill them in." (04C, male, 59 years, treatment group)

One participant in the treatment group felt the questionnaires were a helpful, reflexive tool:

"[The questionnaires were] very informative. I've never been asked all those sorts of questions before, but, you know, they drew from me the sort of things I never knew I'd be asked." (21C, male, 56 years, treatment group)

Two participants (05C and 17C), who did not return interim questionnaires by post, did not reported reasons or difficulties in completing the questionnaires. Participants described no issues related to travel to the study site for assessments, or the environment for completing assessments.

Acceptability of the treatment and attention-control interventions

The format and delivery of the intervention was acceptable to participants in both groups, who enjoyed the home visits and added support through follow-up telephone calls:

“I think it was better done at home, just in your own surroundings, really – [I felt] more relaxed and more secure.” (05C, female, 59 years, treatment group)

“[The telephone calls] were helpful and important, and it is because we had that closeness where [the physiotherapist] has come to my home, and we spoke and went through the programme, that, you know, the relationship exists where she can call and say, ‘How did you get on?’” (21C, male, 56 years, treatment group)

Participants also reported having ample time with the physiotherapist as crucial to the experience, and to building a meaningful therapeutic relationship:

“There’s more time, she’s more relaxed...and so I’m more relaxed.”
(02C, male, 75 years, attention-control group)

“A consultant hasn’t got time to explain all this and you know... she comes, sits and talks with no time limit, so I think it’s helpful.” (13C, female, 55 years, attention-control group)

The physiotherapist recommended home delivery as an opportunity to empower participants, and instil and balanced and collaborative dynamic:

"By being a guest in someone's home, you've automatically empowered them, just through the situation, before you've even had a conversation. It breaks that pattern of entering the role of the clinician dictating, or telling a patient what they ought to do."

(physiotherapist)

However, some participants also welcomed the option of attending intervention sessions at a medical centre:

"I would have gone to the hospital...it's nice to get out anyway." (17C, male, 69 years, treatment group)

One individual, who subsequently joined a centre-based exercise programme, felt home-visits were acceptable, but suggested a hospital visit might feel more formal, and would add significance to the experience, potentially supporting his commitment, and adherence to the programme:

"I think if you do it in a hospital environment, it has more weight. It is more official – 'Right, you're in a hospital, you're being treated'."

(04C, male, 59 years, treatment group)

Coupled with the core sessions delivered during home visits, the physiotherapist felt that booster follow-up telephone calls were crucial for those participants who might have progressed more slowly toward behaviour-change:

"I do feel that people responded at different rates, which is why the booster call is really important for the people who maybe took longer to come around to that self-awareness, and a decision that they do actually want to get a handle on this." (physiotherapist)

From participants' perspectives, booster calls provided reassurance and motivation, and helped to maintain a therapeutic relationship with the physiotherapist:

"I think that was really, really good, and it kind of made you feel a little, 'Yeah, someone's thinking about me. I'm important.'" (04C, male, 59 years, treatment group)

"It's a good follow-up in that sense, that makes you pay a bit more attention because there can be slippage between the first interview. You need a little [prompt] every now and then!" (02C, male, 75 years, attention-control group)

"She reminds me how I'm doing and, you know, so it helps you to know she's going to ring to make sure I stay in control." (13C, female, 55 years, attention-control group)

The clinician felt that the booster follow-up might have been easier to deliver and more effective if additional structure had been provided, in the form of a script including BCTs:

"I felt [the phone calls] could have been expanded... what would be nice is, if there was an additional script that you could add in, particularly for individuals who were not successful in their attempts [at behaviour change], and to be able to refer back to the motivational process again." (physiotherapist)

Overall, participants across groups reported the intervention content as relevant, and felt they had gained positive and useful advice or information from the programme:

"It turned out to be quite informative and... you know, I've learned a lot from it." (21C, male, 56 years, treatment group)

However, some participants (02C, 05C) felt that the experience might have also been useful earlier in their diagnosis, or potentially more suitable for individuals with less healthy lifestyles, as they were already actively walking or looking after their diet:

“Clearly it would have been better seven years ago, when the condition was first highlighted by the doctor.” (02C, male, 75 years, attention-control group)

“I think [the advice] was very good...I mean as far as you know, walking. But then again, I knew that I should walk so they didn’t tell me anything that I didn’t know.” (08C, female, 73 years, treatment group)

“Because I am aware of my daily lifestyle, I didn’t feel that it was totally necessary to follow the plan rigidly so that’s why I suppose I didn’t.” (24C, female, 78 years, treatment group)

The physiotherapist reported the challenge of supporting individuals who described a regimen of walking to consider further behaviour change:

“A challenge I found, particularly in the walking group, was that I could sense some individuals thinking, ‘walking is walking’. On the surface, they were motivated to walk for their health, and they didn’t really grasp that walking was something they needed to do in excess of what they were already doing, given that it wasn’t making a difference.” (physiotherapist)

Some participants benefited from this approach and from learning that they could change their current walking behaviour to potentially improve their health:

“It gets you to think to yourself, ‘Don’t be lazy, you can do more’. And the more you do, the better your condition will be, demonstrating that the more effort I put in, the better things would turn out.” (03C, male, 72 years, treatment group)

However, the physiotherapist reported a range of participants at varying stages of understanding about their condition and motivation for behaviour change, and was able to tailor delivery accordingly:

“There was a wide range of people, some who didn’t need too much education, who knew why walking is something they should be doing, and that made the job much easier for me. It was just a case of fine-tuning what they should be doing and it was a very collaborative and quite easy process.” (physiotherapist)

By contrast, the physiotherapist found some individuals required greater encouragement or persuasion that walking was beneficial, and took more time during Session 1 to address treatment cognitions:

“There were people who were very focused on the fact the medical intervention was needed, and my response to that was...trying [to provide information] in a different way, to find different avenues that might allow them to get on board the fact that [walking] could be an option, even in tandem with medical intervention.” (physiotherapist)

Participants who reported no or limited previous attempts or experiences of walking also frequently reported benefits of receiving the treatment, suggesting that the physiotherapist’s attempts at framing the intervention appropriately for these individuals was successful.

Most participants enjoyed setting and agreeing goals, and found it a useful activity (13C). However, one participant did not enjoy the additional “form filling” (15C) required when

completing the action planning worksheet with the physiotherapist. Another participant, in the treatment group, felt that the action planning worksheet was not suitable, and that the process of writing down her goals and specific plans was a “total and utter waste of time” (08C, female, 73 years, treatment group).

Another participant found action planning difficult because she was already engaging in a degree of routine activity, over and above what the plan entailed:

“Because I am aware of my daily lifestyle I didn’t feel that it was totally necessary to follow the plan rigidly so that’s why I suppose I didn’t.” (24C, female, 78 years, treatment group)

The clinician also reported challenges in goal setting with some participants, and a sense that it was initially perceived as somewhat repetitive and unnecessary:

“I felt almost like I had to apologise for the fact that we were form-filling...but doing it, and having [goals written] on paper is very useful...and I think people actually got on board with the form, once we got going.” (physiotherapist)

However, the physiotherapist felt that the goal setting process was important, and that documenting goals in particular helped draw specific and concrete plans from participants:

“Writing [goals] down is almost making them a sort of binding contract, and there was certain hesitation, and for people to say, ‘Oh, I am actually agreeing to do this’.” (physiotherapist)

This notion was corroborated by some participants who felt they benefited from setting and agreeing goals and plans:

"I think it is a good idea to have a programme, which we set out together on how to do walking, and I signed up to." (03C, male, 72 years, treatment group)

Perceived expectations and outcomes of treatment and attention-control

Participant motivation for joining the study included anticipated benefits to themselves, to others with IC, to research in this area, or the individual researcher.

"I might glean something from being involved that might help me, some clarification about the problem, and some knowledge about it."
(02C, male, 75 years, attention-control group)

"I thought, 'If this is going to lead to something that helps other people, because you provide positive advice and a way of doing things, then it is well worth doing'." (03C, male, 72 years, treatment group)

In addition, some participants in the attention-control group reported having "nothing to lose" as a reason for deciding to take part:

"I thought, 'Well, there's nothing to be lost and possibly something to be gained'." (02C, male, 75 years, attention-control group)

By comparison with their expectations, which were general and equivocal, participants described specific outcomes, including a positive impact on their psychological and emotional well-being, and on the uptake of healthy behaviour, and walking ability.

Across both the treatment and attention-control groups, the intervention had instilled personal control and the belief that one's own actions can affect their condition:

"I know that what food I take and what I do, it does affect...my whole diet affects me, because 'You are what you eat', aren't you?" (15C, female, 65 years, attention-control group)

"Being part of this programme has meant that I'm constantly aware that the result of whatever it is that I'm doing goes toward something." (04C, male, 59 years, treatment group)

Those in the treatment group reported increased self-confidence, knowledge, and motivation:

"It empowered me, made me think 'Yes, I have to run with this as the next best thing for me and my condition.' So the advice and what I've had from you guys, it's my way forward now." (21C, male, 56 years, treatment group)

"I had no knowledge of what to do, until I came to see yourself and the physiotherapist. I improved mentally and physically. I am getting better." (17C, male, 69 years, treatment group)

Across both groups, participants reported increased beliefs that they ought to walk more as a result of the intervention:

"It's highlighted the fact that I do need to exercise. It's brought that home to me a little bit more." (04C, male, 59 years, treatment group)

"In my mind, I was saying, 'Ah yes, you're right, I should perhaps do a bit more walking, or a bit more of this or less of that.'" (02C, male, 75 years, attention-control group)

However, participants in the treatment group only reported an understanding of the link between walking and their condition, the potential outcome of walking for their IC, and an understanding of why they should walk more:

"When the pain is there, I can walk through it now, because I understand why it is there. I never knew before." (17C, male, 69 years, treatment group)

"I'm helping the circulation and, in doing so, in walking and exercising, I'm helping to keep the blood vessels open." (24C, female, 78 years, treatment group)

Participants across both groups reported increased walking as a result of the intervention.

However, the treatment group reported specific behaviour change:

"I'm trying to do one hour per day on most days...I know from past experience I expect to have some discomfort after 5 or 10 minutes, but just to keep going." (03C, male, 72 years, treatment group)

By comparison, those in the attention-control described broad lifestyle changes, or attempts to change:

"I've been exercising more, I've changed my eating habits, my diet, I've lost weight, I can walk further and generally speaking, I feel as if I'm making a contribution to improving my overall health." (04C, male, 59 years, treatment group)

Some participants in the treatment group reported the ongoing challenge of walking, despite the intervention instilling positive beliefs:

"Yes, I do agree with what you've been saying, sort of thing, telling me to walk for 30 minutes, but I find it very difficult." (05C, female, 59 years, treatment group)

One individual, who joined a supervised centre-based programme following participation in the behaviour-change intervention, described the challenge of translating positive beliefs to behaviour:

"It's helpful to encourage you and to educate you to the fact you need to be doing it, but it doesn't make you do it." (04C, male, 59 years, treatment group)

Most, but not all, participants in the treatment group reported explicit benefits to their IC and improved walking ability:

"I can walk further, with less discomfort than I could when it all started." (03C, male, 72 years, treatment group)

"The pain has subsided greatly. It still tingles here and there, but nothing to what it was." (17C, male, 69 years, treatment)

"It hasn't got any better for me, and I'm not exactly lazy." (08C, female, 73 years, treatment group)

By contrast, those in the attention-control group reported physical benefits including weight loss or feeling better in themselves generally, with no clear benefits to improved walking ability.

"I feel that, um, my legs are slightly better than they were, but it is very subjective. I can't see it going away, basically." (02C, male, 75 years, attention-control group)

"Hopefully, one day, something might improve. But it hasn't done so far because they haven't got better, my legs." (12C, male, 90 years, attention-control group)

Role of the physiotherapist as a person and professional

Participants reported personal qualities of the physiotherapist, which resulted in a positive experience of the intervention. Specifically, they reported the physiotherapist as knowledgeable, interested, and friendly, and that these qualities were different from other healthcare professionals they had encountered before, and were important to benefitting from the programme:

"She wasn't like a doctor, she was like, yeah, friendly." (13C, female, 55 years, attention-control group)

"She was very sociable, and amenable, which put me at ease. It was almost like having a chat with a friend if you like, with some medical stuff thrown into it." (03C, male, 72 years, treatment group)

"She's such a positive person, and, she makes you think that she is really interested and really cares. I think she's excellent." (04C, male, 59 years, treatment group)

Participants reported a physiotherapist, in general, as someone who is suited to deliver this type of intervention:

"I don't think there is anyone better qualified than [a physiotherapist], somebody who is clearly interested in making people exercise." (04C, male, 59 years, treatment group)

"It's good physiotherapy. I mean, she's not there to pull me about and manipulate my bones and body, because there is nothing she can do in that way. So the verbal conversation and the talking and the information on how the blood flows around the body – it's good." (21C, male, 56 years, treatment group)

From the physiotherapist's perspective, the intervention was suitable for delivery by an allied healthcare professional, and particularly by physiotherapists:

"Psychologists are going to find that this is a good intervention, but I don't see why physiotherapists shouldn't have this training. I think that physiotherapists are in a good position to be able to deliver this kind of information, and need to have the experience of working with people, and understanding that there is a psychological role before you begin to learn these skills." (physiotherapist)

Participants and the physiotherapist described a collaborative relationship, which had positive outcomes for individuals with IC:

"The work that we have done together has made me feel better, and I do. The main problem that I went [to the hospital] for has subsided since working with [the physiotherapist]. (17C, male, 69 years, treatment group)

In addition, the physiotherapist reported developing a therapeutic stance that enabled a collaborative relationship to develop:

"[The experience] allowed me to give more power to the individual, rather than lecturing them on what they should be doing. I felt that I could get to know [the participant], and to understand them, and develop more of a sort of collaborative or empathic relationship."
(physiotherapist)

Overall, participants reported enjoying the experience of the study, and the intervention. Participants expressed that they would recommend the intervention to others with PAD, and that the opportunity should be made available to others:

"I feel very strongly that it, it's not just a case of recommending it. I think it should be a facility that's available, that, uh, the vascular surgeons say to people, 'Hey, listen, we've got a programme I want you to join that will help you', rather than, 'You need to exercise'."
(04C, male, 59 years, treatment group)

"I think [the programme] should be wider, a bit more known. I'm just really happy that I have the knowledge you've given me, and I think anybody going through this thing should come and have a chat with you." (17C, male, 69 years, treatment group)

8.4 Discussion

This study demonstrated the acceptability of a randomised trial evaluating a behaviour-change intervention targeting walking to participants with IC and a physiotherapist.

Participants reported home visits as a convenient alternative to a hospital-based programme, and the home environment facilitated a collaborative relationship between the physiotherapist and participant. Supervised centre-based programmes are limited in availability and challenging to implement (NICE, 2014b), whereas a home-based programme reduces the burden of travel required by the patient to attend a centre for exercise (Galea et al., 2008), and may improve adherence, in the long-term, to healthy lifestyle choices, such as a regimen of self-directed walking (Ashworth et al., 2005).

In adjunct to home visits, participants and the physiotherapist recommended telephone booster calls, which participants anticipated, and which supported their pursuit of agreed goals and action plans. Face-to-face contact and booster follow-up telephone calls that reinforce previous intervention content, are components of exercise interventions associated with adherence following programme completion (Fjeldsoe et al., 2011). Booster follow-up telephone calls helped to maintain physical activity and self-reported habit strength 6 months following centre-based cardiovascular or orthopaedic rehabilitation in a randomised trial

including 1166 participants, and the effect of the booster follow-up on physical activity was mediated by changes in self-efficacy, action planning, and satisfaction with exercise outcomes (Fleig et al., 2013). However, these booster follow-ups were delivered by student researchers, and followed a centre-based programme. By contrast, participants in the present research reported the importance of establishing a relationship with the physiotherapist prior to receiving the booster telephone calls, suggesting a key feature of the current intervention, which could enhance the effectiveness of telephone boosters. This is consistent with evidence that healthcare professionals are salient normative referents within the social network of individuals with IC (Chapter 6). The physiotherapist in the present study recommended greater structure to booster telephone calls, including a script to support the dialogue with participants, which could incorporate BCTs shown to be effective, including reinforcement, review and revision of goals, and problem solving (Fleig et al., 2013).

Outcomes of the intervention in terms of information, knowledge and improvements in psychosocial variables were reported by participants in both the treatment and attention-control group. While the attention-control participants reported increased healthy behaviour, including diet and walking, the treatment group were more specific in detailing walking outcomes, both in terms of the volume of activity and perceived walking ability. Findings suggest that the attention-control was acceptable to participants, and was perceived as credible and potentially beneficial to participants, which are criteria for an attention-control (Freedland et al., 2011). However, the possibility of contamination of the attention-control, including delivery by the same clinician and transfer effects of dietary behaviour change to walking (Chapter 7) cannot be ruled out.

8.4.1 Methodological considerations

A strength of this study is the inclusion of a purposive sample of representative participants from both the treatment and attention-control groups who provided in-depth, narrative accounts of their experiences. However, sampling did not take into account treatment history, and no participants had undergone revascularisation previously. Feedback from individuals

with IC reflecting a range of treatment histories (e.g., conservative management and/or revascularisation) should be included during patient and public involvement for a definitive trial.

The interviewer (MGH), who was blinded during outcome assessment for the feasibility study (Chapter 7), was unblinded to group allocation for the purpose of conducting interviews, and this may have influenced data collection. However, the investigator followed the same topic guide during interviews with participants in the treatment and attention-control groups. In addition, data was transcribed and primary analyses conducted by an independent investigator (PD), which were validated by the interviewer (MGH) and a third investigator (LMB).

Data reflect the experiences of only one physiotherapist, and the interactions between participants with just one physiotherapist. The transferability of findings across physiotherapists is limited, and there may be qualities of the individual identified by participants in this study which may differ between clinicians, for example, past clinical experience, communication skills, and willingness to engage with counselling-based physiotherapy.

8.4.2 Conclusions

- The acceptability of a randomised trial comparing a home-based walking programme and attention-control targeting dietary behaviour change was reported by participants with IC and a physiotherapist.
- Participants and the physiotherapist reported the importance of establishing a collaborative relationship, which was facilitated by delivery within the home environment.
- Booster telephone session were an important aspect to the intervention, although the physiotherapist invited greater structure to sessions to facilitate delivery and maximise effectiveness.

Chapter 9. Thesis discussion

Walking is an effective but underused treatment for IC. Consistent and strong evidence demonstrates that walking can improve exertional symptoms and increase walking capacity by up to 200% (Lane et al., 2014). In addition, walking contributes to overall daily physical activity, which is associated with reduced cardiovascular morbidity and mortality, and improved physical functioning among individuals with IC (Garg et al., 2009; Garg et al., 2006). However, people with IC do not engage in sufficient walking to improve their health (Galea et al., 2008). Limited access to supervised centre-based programmes is a barrier to short-term benefits of walking, and simple walking advice from a healthcare professional does not increase self-directed walking (Bartelink et al., 2004; Makris et al., 2012). Long-term health gains require adherence to a regimen of walking as a self-management strategy and lifestyle change. Theory-driven behaviour-change interventions that are tailored and delivered in the home environment could bridge the gap between scarce centre-based programmes and ineffective walking advice, and facilitate walking adherence and improvements in walking ability among individuals with IC.

Therefore, this research developed and evaluated a behaviour-change intervention targeting theory-based cognitions to facilitate self-directed walking in people with IC. Consistent with MRC guidelines (Craig et al., 2008), the programme of work sought to review the existing evidence base, identify and develop theory, model processes and outcomes, and test procedures for a larger study. These guidelines were implemented through a series of distinct but complementary studies incorporating qualitative and quantitative methods: 1) a systematic review of the existing literature on theory-based BCTs that have been applied to walking interventions for IC; 2) a qualitative exploration of experiences and beliefs about their illness and walking treatment among individuals with IC; 3) a cross-sectional evaluation of

constructs defined by the TPB and CSM as determinants of walking intention and objective walking ability; and 4) an acceptability and feasibility study of an RCT of a physiotherapist-led home-based behaviour-change intervention targeting walking among individuals with IC.

9.1 Summary of key findings

9.1.1 Systematic review of behaviour-change interventions targeting walking in people with IC

A systematic review identified six studies reporting behaviour-change interventions targeting walking in people with IC (Chapter 4). Most studies were highly susceptible to bias, and reported varied effects on the primary outcome, MWA, and on secondary outcomes including PFWA, self-reported walking ability, and walking behaviour. Overall, 11 BCTs (Michie et al., 2011a) were identified across included studies. Barrier identification and problem solving, self-monitoring, and feedback on performance were applied frequently, and were included in two effective interventions (Cunningham et al., 2012; Gardner et al., 2011). However, most studies were not informed by health psychology theory explicitly, and none evaluated theory-based mechanisms of change, providing little assurance that BCTs were delivered consistently and could explain findings.

9.1.2 Qualitative study exploring individual experiences of and beliefs about walking in people with IC

A qualitative study (Chapter 5), using the Framework Method, and employing semi-structured in-depth interviews including 19 individuals with IC, revealed two key themes. First, walking is an overlooked self-management strategy among people with IC, regardless of the perceived consequences of their condition. That is, for individuals who reported their IC as benign, symptoms could be overcome without the perceived need for any treatment, including walking. By contrast, individuals who reported their IC as severe expressed a strong emotional response, including feeling helpless, and a lack of personal and treatment control over their condition, and hence did not embark on regular walking. Second, individuals with IC reported a

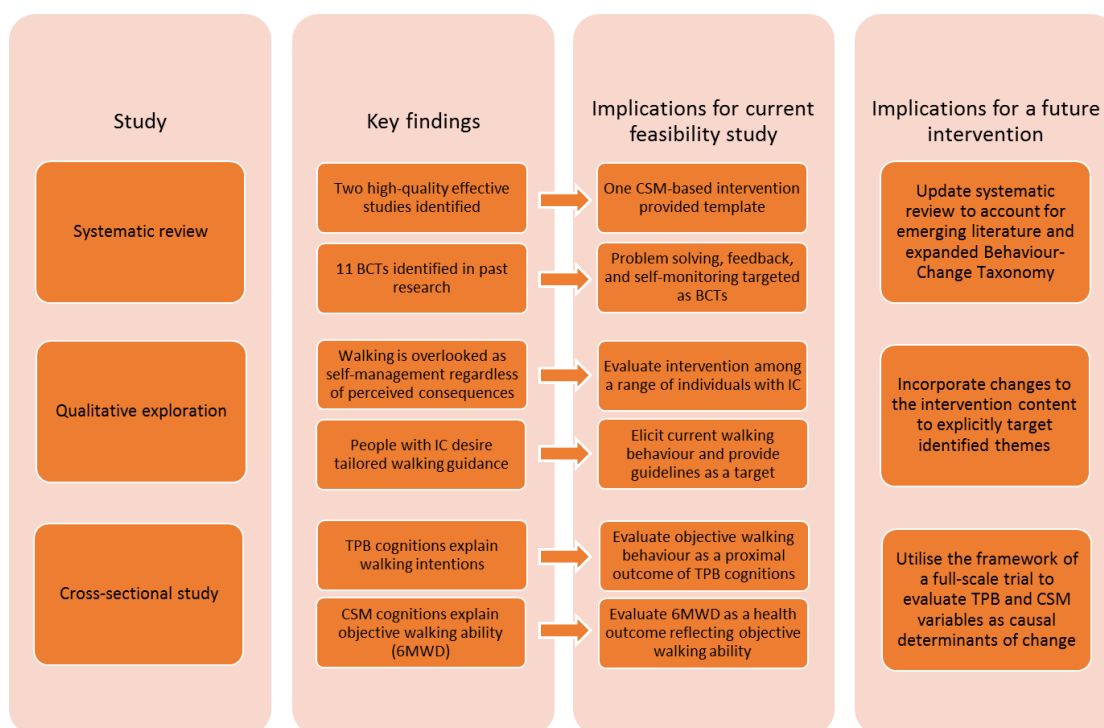
desire for tailored walking guidance. A lack of clear guidance contributed to findings that individuals were not achieving walking guidelines, and to reports of limited purposeful or monitored walking, barriers to walking to intensity, and varied outcome expectations of walking among participants.

9.1.3 Cross-sectional observational study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD in people with IC

Data from a cross-sectional analysis including 142 individuals with IC (Chapter 6) demonstrated that, overall, 73% and 28% of the variance in walking intentions and objective walking ability (6MWD), respectively, was explained. Past walking behaviour was an important predictor in both models, and walking treatment cognitions defined as TPB constructs were better at explaining walking intention, whereas illness cognitions defined as CSM constructs explained 6MWD. Attitude, subjective norm, and perceived behavioural control regarding walking, and perceived consequences of PAD, made independent contributions to explaining walking intention, and risk factor attributions, illness coherence, treatment control, and personal control over PAD were illness cognitions that contributed to explaining 6MWD.

The aim of the first three studies was to evaluate and establish an evidence base for employing the TPB and CSM as frameworks for developing and evaluating the feasibility of a walking intervention for IC, and to identify suitable BCTs that could facilitate walking. A strength of this work was the use of mixed methods to establish an evidence base; however, a challenge of mixed-methods research involves the integration of findings, drawn from divergent methods and epistemologies. A pragmatic approach was employed, wherein qualitative or quantitative methods were distinct, but corresponding in their overarching goal, to inform the development of a walking intervention. The implications of key evidence from each phase of research toward the feasibility study is summarised in Figure 9.1.

Figure 9.1 Translation of key findings to the development and execution of the feasibility study, and implications for future research



BCTs, Behaviour-change techniques; CSM, Common Sense Model of Illness Representations; IC, intermittent claudication; TPB, theory of planned behaviour.

9.1.4 Feasibility and acceptability studies of a physiotherapist-led behaviour-change intervention targeting walking in people with IC

The feasibility of an RCT informed by the TPB and CSM, and targeting walking in people with IC, was demonstrated in Chapters 7 and 8. One high-quality, effective intervention, informed by the CSM, provided a template for the current study (Cunningham et al., 2013; Cunningham et al., 2012); however, that study included only newly diagnosed individuals with IC, found no treatment effect on key theory-based constructs, did not report on treatment fidelity, and included a usual care control, which limits the interpretation of findings. In addition, the intervention was delivered by a researcher, so the feasibility of implementing the intervention in clinical practice was not demonstrated.

Unlike previous research (Cunningham et al., 2013; Cunningham et al., 2012) the present study sampled the wider population of individuals with IC to include those who had undergone revascularisation, included an attention-control arm which supports the validity of findings, and assessed theory-based process measures defined by the TPB and CSM at three time

points. In addition, objective walking was assessed as the outcome, extending our knowledge of the applicability of the walking intervention among individuals with IC. A physiotherapist was trained to deliver the intervention, and affirmed the acceptability of this process (Chapter 8).

Most feasibility criteria were achieved, demonstrating study retention (>60%), compliance to the intervention (>60%), utility of the MITI Code as a fidelity assessment tool, and a positive effect of the intervention on objective walking behaviour (Hedges $g=0.39$, 95% CI -0.47, 1.25). In addition, acceptability of the protocol was confirmed based on narrative accounts of participants and the physiotherapist in a nested qualitative study (Chapter 8). However, rates of missing baseline pedometer data and post-intervention questionnaire data were higher than expected. Reasons for missing data were explored further in the qualitative interviews. Participants reported the pedometers were comfortable and non-intrusive, but some individuals (e.g., 04C, 09C, and 21C) expressed difficulties in remembering to wear the device. In addition, while individuals felt equivocal about completing questionnaires, some forgot to complete these at home or reported returning them, although they were not received. Strategies to remind participants to wear their pedometer and to complete interim questionnaires at home (e.g., text reminders, use of incentives) should be employed in a definitive trial.

Walking behaviour increased by approximately 60 minutes/week following the intervention, however, this is below recommendations to walk for at least 30 minutes on at least 3 days/week (i.e., at least 90 minutes/week), and might explain the lack of improvement in 6MWD, although the study was not powered to evaluate hypothesised effects. This contrasts with previous findings, in which a similar intervention increased walking by mean 1358.4 steps (approximately 95 minutes/week) (Cunningham et al., 2013; Cunningham et al., 2012); however, that study did not evaluate objective walking ability, so it is unclear whether achieving the appropriate volume of walking led to improvements in clinical outcomes. In

addition, that study did not evaluate change in targeted cognitions. Risk factor attributions, illness coherence, treatment control, and personal control regarding PAD were CSM constructs associated with 6MWD, and which were targeted by the present behaviour-change intervention alongside other CSM variables, but only treatment control and coherence demonstrated positive changes following treatment, so other CSM variables may require additional emphasis in future interventions.

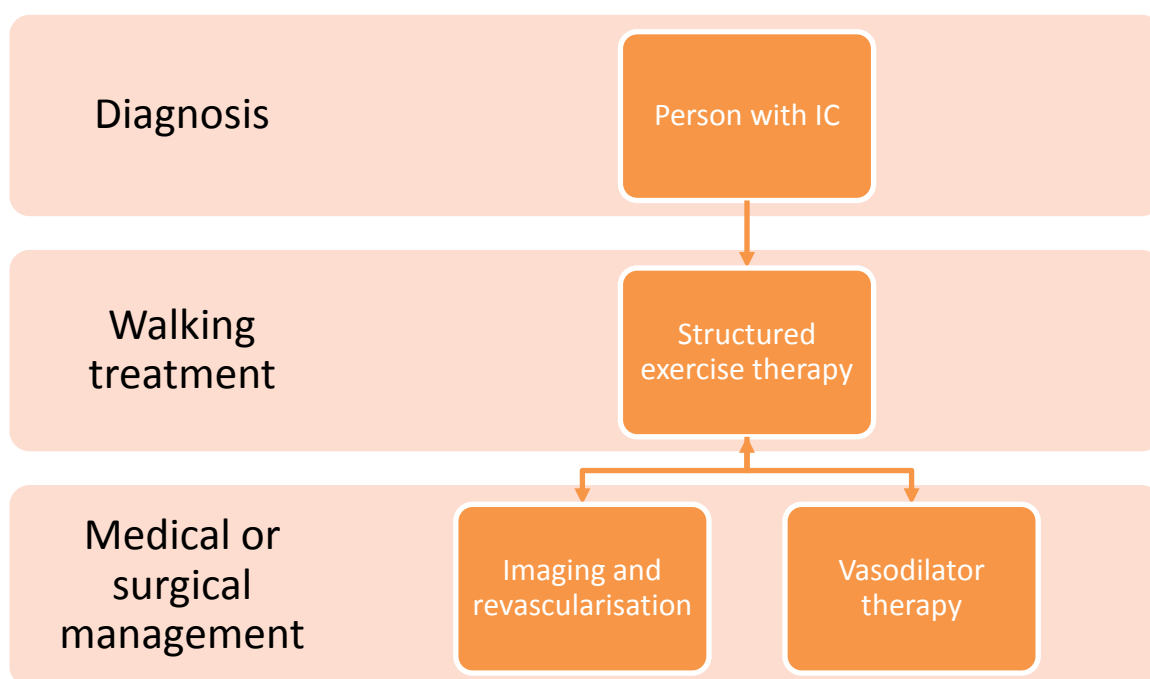
9.2 Implications for management of individuals with IC

Supervised centre-based exercise programmes are a key quality improvement area and a priority commissioning action identified by NICE (2012). Currently, there is a lack of available programmes for clinicians to refer people with IC, and the cost of initiating new programmes is a barrier (NICE, 2014b), despite evidence of the cost-effectiveness of exercise therapy for IC once a programme is in place. However, a potential threat to the effectiveness, and cost-effectiveness, of supervised exercise therapy is adherence, which has not been demonstrated over the short- or long-term following discharge (Birmingham et al., 2013). Only approximately half of individuals adhered (e.g., attended $\geq 80\%$ of session) to supervised exercise therapy, with nearly 40% dropping out within 4 weeks of initiating the programme (Guidon and McGee, 2013). However, that intervention provided exercise alone without BCTs, was available only on a twice-weekly predefined schedule without flexibility, and identified participants from patient records who may not have been actively seeking treatment for their IC. In addition to low participant attendance (i.e., adherence), the long-term effectiveness of supervised exercise therapy is unknown, as there is limited evidence that individuals maintain regular self-directed walking upon programme completion. Assuming no difference in long-term adherence after 1 year, Birmingham et al. (2013) reported an Incremental Cost-Effectiveness Ratio of £1608 per Quality-Adjusted Life Year (QALY) gained, which resulted in a 25% likelihood that walking advice would be cost-effective at a willingness to pay £20,000 compared with supervised exercise therapy. Simple walking advice is ineffective, and data suggest that evidence based on short-term outcomes may over-estimate the cost-

effectiveness of supervised exercise therapy, and highlights the potential for lost expenditure on programmes that do not support adherence to walking behaviour. Until effective home-based walking programmes are established, which support adherence to walking, it may be impossible to determine the cost-effectiveness of such programmes against alternative treatment options. The current research begins to address this gap by identifying BCTs that could facilitate regular self-directed walking, and employing a robust theoretical underpinning to the intervention development and evaluation, which is informed by in-depth narrative accounts of the experiences and beliefs of individuals with IC. In addition, this research extends the role of physiotherapists in IC management. Employing allied health professionals, such as physiotherapists, to deliver this brief intervention in participants' homes, could minimise the cost of treatment compared with supervised exercise therapy, and facilitate commissioning within the NHS. In addition, participants reported a positive therapeutic alliance with the physiotherapist (Chapter 8), which may improve adherence to walking, also contributing to the cost-effectiveness of the intervention.

Current NICE pathways for care recommend a supervised walking programme as a first-line treatment strategy for IC, which precedes medical and surgical management (NICE, 2012). However, there is scope for exercise therapy, particularly walking, to be included alongside other management strategies to improve long-term outcome, and support rehabilitation post-revascularisation. The current research demonstrated the expanded role of a structured home-based walking programme for individuals with long-standing IC, including those who had undergone revascularisation. Therefore, the pathway for management of individuals with IC should not terminate at medical and surgical management. Instead, a bi-directional pathway between walking and medical and surgical management may provide patients and clinicians with greater flexibility to facilitate the adoption of healthy lifestyle changes by providing structured home-based walking programmes before, alongside or after revascularisation (Figure 9.2).

Figure 9.2 Proposed bi-directional pathway between structured exercise therapy and medical or surgical management of IC



National Institute for Health and Care Excellence (2015). Adapted from 'Managing intermittent claudication in people with peripheral arterial disease'. Reproduced with permission.

9.3 Implications of findings for physiotherapy practice

Studies of home-based walking therapy for people with IC have reported delivery by a nurse, researcher, or psychologist (Galea et al., 2013; Al-Jundi et al., 2013). Exercise and physical activity prescription is a key management strategy for physiotherapists, and training in communication skills and BCTs are core components of pre-registration physiotherapy training, so qualified physiotherapists require minimal training to be able to deliver this intervention. This study demonstrated that training a physiotherapist in BCTs, including motivational interviewing, was feasible. Training was brief comprising a total of 15 hours of formal contact, including a 1 day course in motivational interviewing certified by the British Psychological Society, role play with feedback, and ongoing supervision of recorded sessions. These techniques have demonstrated effectiveness in training clinicians to deliver health psychology interventions (Perryman, 2014). The programme extends practice by providing an alternative to group-based interventions, to provide a more tailored, individual treatment approach.

A physiotherapist was considered by participants as the appropriate healthcare professional to deliver the intervention, and a positive therapeutic alliance was established based on participant reports, which could support treatment adherence (Cohen, 2009). The physiotherapist confirmed the acceptability of the intervention and training, and offered areas for improvement, including greater structure for the booster telephone session, which should be incorporated to the intervention materials and training package. While this study demonstrated the feasibility of the training programme, it did not aim to evaluate the effectiveness. A full-scale trial is required to evaluate the clinical and cost-effectiveness of the intervention, and further research should be undertaken to evaluate the volume and content of training required to achieve competency prior to treatment delivery.

9.4 Contributions to theoretical understanding of walking among people with IC

The health behaviour change literature is dominated by a small number of theoretical frameworks, including the TPB and CSM (Painter et al., 2008). Many theories employ constructs and pathways that conceptually or statistically overlap, and there is potential to compare constructs, determine the most robust models, and to inform the development of new models (Sniehotta et al., 2013; Noar and Zimmerman, 2005). In addition, existing theories are incomplete, explaining only small to moderate variance in health behaviour (Armitage and Conner, 2001; Hagger and Orbell, 2003), and there is scope for extending theories if new variables can be identified that add to the predictive utility of a framework, such as the TPB (Ajzen, 1991).

Cross-sectional data (Chapter 6) support the TPB for explaining walking intentions in people with IC, and expand our theoretical understanding of this domain by providing the first evidence that CSM variables account for objective walking ability unexplained by the TPB, and that this pathway is not directly mediated by intention. This contrasts with a previous study, which hypothesised that intention would mediate the effect of CSM constructs on self-reported physical activity at 2 months following cardiovascular rehabilitation, but found no

effect of either model on the outcome, and only perceived behavioural control and timeline cyclical emerged as independent predictors (Sniehotta et al., 2010). However, that sample was small, predominantly male, and psychometric properties for the measure of illness perceptions were low. In addition, physical activity was assessed by self-report. To date, no other studies have been identified which apply the TPB and CSM together to explain objectively measured physical activity.

While the TPB suggests that intention is a prerequisite to behaviour, the present findings, and those of Sniehotta et al. (2010), are consistent with the wider literature demonstrating an “intention–behaviour gap” (Orbell and Sheeran, 1998). A number of factors have been explored as potential moderators of the intention–behaviour relationship (e.g., intention stability, anticipated regret, and conscientiousness); however, the evidence is inconclusive, and based primarily on healthy samples (Rhodes and Dickau, 2012b). It is possible that, in the context of walking in people with IC, TPB and CSM constructs interact so that intenders with positive illness cognitions are more likely to engage in walking. The cross-sectional study described in Chapter 6 was not designed or powered to evaluate this hypothesis, so future research could explore possible interactive effects of intentions and illness cognitions on walking.

It may be that illness cognitions have an indirect effect on intention by contributing to the formation of attitude, subjective norm, and perceived behavioural control. Horne and Weinman (1999) suggested that beliefs about illness may influence choice of treatment, outcome expectations of treatment, and adherence. Illness cognitions determine beliefs about the necessity of and concerns about pharmacological treatment (Horne and Weinman, 2002); however, this pathway has not been explored using treatment beliefs defined by the TPB, or in the context of walking treatment.

Self-regulatory processes have also been proposed to bridge the gap between intention and behaviour. The CSM is a self-regulatory model, and suggests that a behavioural response

(e.g., walking) contributes to a cognitive and emotional feedback loop which serves to achieve individual standards, or goals, for regulating a health threat (e.g., reduced symptoms, improved walking ability). Although the TPB is not explicitly a self-regulatory model, behavioural attempts provide a source of information, which, in turn, may contribute to changes in attitude, subjective norm, perceived behavioural control, and intention (Ajzen, 2002b). Action planning and action control are self-regulatory processes which are proposed to act as moderators or mediators of the intention–behaviour relationship, and which were evaluated in the feasibility study (Chapter 7). These variables may be important mechanisms, which could be common to the TPB and CSM, and which may support the translation of intentions or illness cognitions to behaviour by facilitating automatic processing of decisions to walk. Therefore, action planning and action control should be considered in future research which combines these models to explain walking behaviour, and included in further evaluations of the current intervention.

Findings suggest different contributions of the TPB and CSM toward understanding walking intention and objective walking ability in IC. While it might appear as though the TPB and CSM are divergent or incompatible, alternately it is possible that the models are underpinned by unique processes, and therefore each contributes independently to understanding walking. The TPB in particular is a general theory of behaviour, and proposes determinants that are proximal to enactment of a behaviour (e.g., walking). By contrast, the CSM models the schematic representation of illness, which encompasses behavioural coping responses (e.g., walking as treatment for IC), and, by explicitly accounting for illness cognitions, might better correspond with a disease-specific behavioural outcome, such as the 6MWD. In addition, the 6MWD might represent a distal outcome of walking behaviour among individuals with IC, which is mediated by angiogenic or arteriogenic mechanisms (Chapter 1), and therefore not captured by TPB constructs (Figure 9.3).

Figure 9.3 Proposed indirect pathway from behavioural determinants defined by the TPB to health outcome, defined as the 6MWD



Adapted from Hardeman et al. (2005) with permission from Oxford University Press. TPB, Theory of Planned Behaviour; 6MWD, 6 Minute Walk Distance.

Further investigation of how the models combine to explain walking may inform intervention development. For example, constructs from the TPB (e.g., attitude, subjective norm, perceived behavioural control) may be targeted in the motivational stage of behaviour change, to increase walking intentions, whereas CSM constructs may facilitate the translation of positive intentions to walking behaviour and improved walking ability. The current intervention incorporated TPB and CSM constructs simultaneously to form a health-behaviour link early in the intervention (Chapter 7), and further research is needed to evaluate whether CSM constructs should be emphasised during the later, volitional phase of behaviour-change, alongside self-regulatory processes (e.g., action planning and coping).

9.5 Frameworks for behaviour-change and implementation to practice

Despite limited empirical evidence for combining theoretical frameworks to explain and understand health behaviours, interventions often draw on multiple theories in their design (Davies et al., 2008; Darker et al., 2009), suggesting a discrepancy between the available theoretical evidence and implementation to practice, and a potential limitation of the available theoretical models. A key problem is the lack of explicit evidence for *how* to apply existing theories during intervention development to target modifiable constructs (e.g., cognitions). Frameworks which transcend theory provide a structure for characterising and designing behaviour-change interventions, and a practical starting point for overcoming the limitations of theory. The present research employed the MRC framework for developing and evaluating complex behaviour-change interventions (e.g., walking programmes for IC), which recommended methods for 1) intervention development (i.e., identifying the evidence base,

developing theory, modelling processes and outcomes) and 2) feasibility testing. The next stages in that process include 3) evaluation and 4) implementation to practice. Evaluation of treatment effectiveness, processes of change, and cost-effectiveness are necessary to justify the adoption of a novel intervention to practice, and can take place before or alongside implementation. MRC guidance outlines “potentially useful” (Craig et al., 2008) approaches to implementation, including stakeholder involvement, accounting for contextual factors, or multifaceted dissemination. However, implementation frameworks exist, which move beyond description of processes to propose determinants (e.g., the Theoretical Domains Framework) (Cane et al., 2012) or theories (e.g., Capability-Opportunity-Motivation-Behaviour [COM-B] Model) (Michie et al., 2011b) that can be applied during implementation (Nilsen, 2015). Behaviour-change is central to implementation, which requires healthcare professionals and patients to adopt and engage with a new treatment; however, implementation frameworks account for factors beyond human agency to include aspects of the context and system within which an intervention is provided (e.g., service provision, legislation, other treatment options). The next stages of this research should assess and evaluate factors influencing the capability, opportunity, and motivation of patients and healthcare professionals to engage with and adopt a new treatment to facilitate walking for IC, and to address potential barriers to implementation alongside an effectiveness evaluation.

9.6 Continued intervention development and evaluation

The feasibility study centred on refinements to an existing study protocol, including intervention delivery, process evaluation, and factors that might influence implementation to practice. However, core components of the treatment itself (e.g., the treatment script and BCTs employed) were adapted from previous research and should be updated based on the findings of this programme of research, and in particular from qualitative evidence (Table 9.1).

Table 9.1 Proposed refinements to a structured home-based behaviour-change intervention targeting walking among individuals with IC

Refinements to the walking intervention based on findings from the current work	Behaviour-change techniques ^a
Elicit participants' previous treatment experiences including revascularisation in order to position walking as a therapeutic strategy in the appropriate context for the individual	Framing/reframing
Define the notion of "walking through pain" including the identification of barriers to walking to intensity and strategies for overcoming these	Instruction on how to perform a behaviour Biofeedback
Reduce negative emotions by providing coping strategies alongside recommendations for walking, particularly among individuals with high perceived consequences of IC	Information about health consequences Salience of consequences Information about emotional consequences Reduce negative emotions
Structure booster sessions to facilitate delivery and maximise opportunities for walking adherence and self-management	Focus on past success Feedback on behaviour Review of goals Discrepancy between behaviour and goal Habit formation Generalisation of target behaviour

^aDefined according to the Behaviour Change Taxonomy (version 1) (Michie et al., 2013).

This research engaged individuals with IC to determine the resonance and readability of intervention scripts and materials, and to evaluate the feasibility of pedometer outcome assessment (Chapter 6). Qualitative interviews provided rich data on the acceptability of the RCT and interventions. However, greater patient and public involvement in advance of a definitive trial is needed to contribute to the acceptability of intervention and study components.

Therefore, the next stage of research should include the following:

- Extended stakeholder involvement, including further guidance from patient experts, vascular specialists, and physiotherapists, to inform refinement of the intervention components and study protocol;
- Development of a comprehensive training programme, incorporating evidence-based training techniques (Perryman, 2014), for dissemination to a wider group of clinicians delivering the intervention;
- Preparation for a complete process evaluation (Moore et al., 2015), including the intervention implementation (e.g., fidelity, dose, and reach) and mechanisms for change (e.g., robust mediation analysis of proposed illness and treatment cognitions), to support interpretation of outcome data;
- A cost–utility evaluation to support the commissioning of a structured home-based exercise programme, including a comparison of long-term (>6 month) outcomes; and
- Application of an implementation framework to identify potential barriers to adoption of a novel intervention by healthcare professionals and patients, and to facilitate translation to practice.

9.7 Methodological considerations

This research addressed NICE recommendations to evaluate beliefs and attitudes of individuals with IC, in order to facilitate behaviour change and inform management strategies (NICE, 2012). MRC guidance for developing and evaluating complex interventions were followed, including the use of mixed methods, which is a strength of this work. Simultaneously, our theoretical understanding of walking in IC was expanded, by testing constructs from the TPB and CSM as determinants of objective walking, supporting the role of the TPB as a robust framework in behaviour-change theory and practice, and demonstrating the scope for elaborating the basic tenets of the model to incorporate illness cognitions.

Limitations of this research included 1) the evolving Behaviour Change Taxonomy, which led to inconsistencies in reporting, and 2) challenges recruiting participants with IC, which meant complete data was not available in time to inform the intervention content, and are described below.

9.7.1 Evolution of the Behaviour Change Taxonomy

A Behaviour Change Taxonomy was employed to identify, evaluate, and report evidence underpinning the current research (Michie et al., 2013; Michie et al., 2011a). However, iterations of the taxonomy are reflected throughout this work, potentially contributing to discrepancies and loss of coherence. The evolved taxonomy has not simply reflected the addition of new components; instead existing BCTs have been relabelled or reclassified, which could contribute to discrepancies in reporting of this thesis. For example, the 26- and 40-item taxonomy defined motivational interviewing as a technique in its own right, and which is a BCT underpinning the current intervention. However, the most recent 96-item taxonomy describes motivational interviewing as a form of the technique, social support. However, reporting “motivational interviewing” provides a more specific account of the intervention content compared with “social support”. Second, while the Behaviour Change Taxonomy is informed by theory, it is not exhaustive, and does not provide explicit guidance for BCTs that map on to TPB and CSM constructs. Therefore, it is possible that walking treatment and illness cognitions salient to individuals with IC are not easily modified by the current armament of BCTs which have been identified and defined. In future, research should not apply the taxonomy as an exhaustive resource, and should contribute to the taxonomy development by identifying techniques that affect behaviour-change via processes consistent with the TPB and CSM.

9.7.2 Recruitment of individuals with PAD

Recruiting individuals with PAD to research is challenging (Guidon and McGee, 2013). The qualitative study included a predominantly White sample, despite attempts to purposively sample individuals from ethnic minorities. However, PAD prevalence is higher among people who are Black (Criqui et al., 2005), and increased comorbid risk factors, including diabetes and

hypertension, are associated with Black and South Asian ethnicities (Bhopal et al., 2007; Meadows et al., 2009). In addition, rates of revascularisation differ by ethnicity (Ahmad et al., 2013). Strategies for identifying and recruiting individuals from ethnic minorities are needed to facilitate research in this area, such as engaging with community or faith leaders, targeting primary care practices in areas servicing high concentrations of ethnic minorities, and ensuring translators are available for individuals who are not fluent in English.

Second, recruitment to the cross-sectional study was slower than anticipated and required an extension of the study, and expansion to a new site. Records maintained between January 2013 and July 2014 indicate a recruitment rate of 18% ($n=116/624$) of total individuals referred for suspected or confirmed IC. It is possible that individuals referred to a vascular surgeon are likely to have progressed PAD (e.g., critical limb ischaemia). Detection and awareness of PAD in primary care is an increasing priority (Burns et al., 2003; NICE, 2012), and future studies should consider identification of individuals with IC at an earlier stage in their care.

9.8 Areas for future research

Updated systematic review. Following publication of a systematic review, at least two RCTs reported behaviour-change interventions that were effective in increasing walking in people with IC (McDermott et al., 2013b; Tew et al., 2014). These recent studies incorporate behaviour-change theory or techniques explicitly, suggesting that health psychology is increasingly being used to inform the development of walking interventions for IC. An update of the systematic review may be required to synthesise new evidence in this area, potentially providing more conclusive evidence for effective components of behaviour-change interventions.

Ongoing theory testing. Robust tests of theory, including larger studies with prospective longitudinal designs, are required that permit the evaluation of latent variables (e.g., structural equation modelling) in order to better understand the causal relationships between walking treatment and illness cognitions in the context of walking with IC. In addition, volitional

aspects of control, for example action planning and action control could be included in a combined model as proximal determinants of behaviour. Another opportunity for theory testing involves RCTs of interventions that include mediational analyses (Noar and Mehrotra, 2011). A fully powered trial evaluating a home-based behaviour-change intervention and employing pre-, interim-, and post-intervention measures of TPB and CSM constructs would complement and extend the existing findings.

Outcome development. Validated, disease-specific measures of self-reported walking behaviour should be developed and used, which reflect the frequency, duration, and intensity of walking activity, and should be coupled with objective walking assessment (e.g., pedometer and 6MWD) to ensure the reliability and validity of data on walking behaviour. The MCID should be established for primary clinical outcomes, including the 6MWD, to provide a benchmark for interventions designed to improve the health of individuals with IC.

Intervention evaluation and implementation. A definitive trial of this intervention is needed to evaluate the effectiveness, cost-effectiveness, and provide a complete process evaluation reporting implementation (e.g., treatment fidelity, dose, and reach) and evaluating mechanisms of impact (e.g., participant accounts, hypothesised mediators) consistent with the latest guidance (Moore et al., 2015).

9.9 Conclusions

- Two high-quality studies supported self-monitoring, feedback on performance, and barrier identification with problem solving as effective BCTs applied to walking interventions for IC.
- Walking is overlooked as a self-management strategy by people with IC, regardless of the perceived consequences of IC. A lack of tailored walking guidance, including information on purposeful walking exercise, walking to intensity, and outcomes of walking for IC could support individuals in achieving walking guidelines.
- Walking treatment cognitions defined by the TPB explain walking intention among people with IC, whereas illness cognitions defined by the CSM explain objective walking ability. Attitude, subjective norm, and perceived behavioural control regarding walking treatment, and personal control, treatment control, coherence and risk factor attributions regarding PAD are salient cognitions.
- An RCT which evaluated a physiotherapist-led home-based behaviour-change intervention targeting walking for IC, which was informed by the TPB and CSM, was feasible, and was acceptable to participants and the physiotherapist.

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Appendix 1

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Appendix 1.1 Ethical approval notice for a qualitative study on experiences of and beliefs about walking for IC and a cross-sectional observational study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD in people with IC

	 National Research Ethics Service NRES Committee London - London Bridge (Formerly Guy's REC) Governor's Hall Suite St Thomas' Hospital London SE1 7EH Telephone: 020 7188 2260 Facsimile: 020 7188 2258
30 August 2011	
Dr Lindsay M. Bearne Lecturer Division of Health and Social Care Research 3.25c Shepherd's House, Guy's Campus Kings College London London SE1 1UL	
Dear Dr Bearne	
Study title:	Increasing walking in patients with peripheral arterial disease: the role of patient cognitions
REC reference:	11/LO/0871
Thank you for your letter of 15 July 2011 and email of 17 August 2011, responding to the Committee's request for further information on the above research and also submitting revised documentation.	
The further information has been considered on behalf of the Committee by the Chair.	
Confirmation of ethical opinion	
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.	
Ethical review of research sites	
NHS sites	
The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).	
Non-NHS sites	
Conditions of the favourable opinion	
The favourable opinion is subject to the following conditions being met prior to the start of the study.	
<u>Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.</u>	
<small>This Research Ethics Committee is an advisory committee to London Strategic Health Authority The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England</small>	

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		30 May 2011
Evidence of insurance or indemnity	KCL	04 August 2010
Interview Schedules/Topic Guides	1	30 May 2011
Investigator CV	Dr Lindsay M Bearn	30 May 2011
Other: Student CV	Melissa N Galea	30 May 2011
Other: Supervisor CV	Professor John Weinman	30 May 2011
Participant Consent Form: Study 2	1	30 May 2011
Participant Consent Form: Study 1	2	15 July 2011
Participant Information Sheet: Study 1	2	15 July 2011
Participant Information Sheet: Study 2	2	15 July 2011
Protocol	1	30 May 2011
Questionnaire: Borg CR10 Scale for Pain		
Questionnaire: Borg Rating of Perceived Exertion		
Questionnaire: Illness Perceptions Questionnaire - Revised		
Questionnaire: Theory of Planned Behaviour		
Questionnaire: Survey of Pain Attitudes		
Questionnaire: Vascular Quality of Life Survey		
Questionnaire: Beliefs About Medicines	1	30 May 2011
REC application	Parts A - D	30 May 2011
Response to Request for Further Information		17 August 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.



Further information is available at National Research Ethics Service website > After Review

11/LO/0871

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely


 **Professor David Bartlett**
Chair

Email: stephanie.hill@gstt.nhs.uk

Enclosures: "After ethical review – guidance for researchers" SL-AR2

Copy to: Karen Ignatian, R & D, Guy's & St Thomas' Foundation NHS Trust



Understanding illness and treatment beliefs of patients with PAD

Participant Information Sheet (15 July 2011)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

Peripheral arterial disease (PAD) can cause leg pain or discomfort, which limits the ability to walk and carry out everyday activities. Walking exercise can lead to improvements, but it can also be painful, and people with PAD often have difficulty keeping up regular walking on their own. A better understanding of the experiences of people with PAD could help us develop programmes that motivate people to walk more and improve overall health.

Therefore, the first aim of this study is to learn more about the experiences, feelings and beliefs of people with PAD with regard to their illness, symptoms and walking exercise. The second aim of this study is to find out whether a brief questionnaire on beliefs about walking exercise is meaningful and appropriate for people with PAD.

Why have I been chosen?

You were invited to participate in this study because you have been diagnosed with PAD and experience symptoms of leg pain ('claudication') when you walk. We hope to include up to 17 participants with PAD in total. This study has been funded by the Dunhill Medical Trust, which is a registered UK charity.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. If you decide to take part you are still free to withdraw from the study at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

You will be asked to take part in an interview with the researcher (Melissa Galea). The interview will last approximately **60 minutes** in total, and will include a discussion of your beliefs, feelings and experiences of having PAD, your symptoms and walking. You will also be asked to complete a brief questionnaire on your beliefs about walking exercise as a treatment for your condition. You will then discuss this questionnaire with the researcher, because we would like to know if it is suitable and applicable to people with PAD.

The interview can take place at your home or at the Division of Health and Social Care Research (King's College London, Guy's Campus), depending on your preference. If you chose to be interviewed in your home, the researcher will visit your address at a mutually convenient time. If possible we would like to talk to you in a space that is private, quiet and without interruption.

What are the other possible disadvantages and risks of taking part?

Taking part in this study involves discussing your illness, symptoms of leg pain and how you feel about walking. There is a chance that talking about some of these things may make you feel discouraged, uncomfortable or distressed. As a participant, you may choose not to respond to a question, or to end the interview at any point with no consequences.

If you have concerns about any aspect of this study, you may contact the researchers who will do their best to answer your questions (contact Melissa Galea 0207 848 6679).

What are the possible benefits of taking part?

By taking part in an interview, you may learn about your own thoughts and beliefs about your condition and its management through open discussion. The information we get from this study may help us to develop a programme that aims to help people with PAD to walk more by targeting important beliefs. It may also help develop a suitable questionnaire for PAD patients on beliefs about walking exercise as a treatment.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without giving us a reason and we will destroy all your identifiable samples, but we would like to use the data (which will not be identifiable) collected up to your withdrawal in the final study analysis.

What if something goes wrong?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs.

Regardless of this, if you have concerns about any aspect of the way you have been approached or treated during the course of this study you may wish to contact the hospital's Patient Advice and Liaison Service (PALS) on 0207 188 8801.

What will happen to the information that is collected from the study?

Any information you provide during the course of the research and any information about you that leaves the hospital will be kept strictly confidential and anonymous and you will not be identified in any way by your responses to study questions. Records of any interviews will be transcribed and the tapes destroyed immediately.

The results of the study will be published in medical journals and presented at medical conferences. Copies of the results can be obtained from the study organiser (Dr Lindsay Bearne) when the study is completed.

What happens now?

You will be contacted by the researcher (Melissa Galea) to discuss whether you would like to participate in this study. The researcher will be able to answer any questions you might still have about participating and an appointment for an interview made at a mutually convenient place and time.

Thank you for taking the time to learn more about this study. If you have any questions please contact:

Melissa Galea (0207 848 6679, melissa.galea@kcl.ac.uk)
Dr Lindsay M Bearne (0207 848 6322, Lindsay.bearne@kcl.ac.uk)
King's College London, Division of Health and Social Care Research
Guy's Campus, London, SE1 1UL

Appendix 1.3 Participant Consent Form for a qualitative study exploring individual experiences of and beliefs about walking for IC



Understanding illness and treatment beliefs of patients with PAD
Consent Form

Participant ID _____

Researchers: Melissa Galea, Dr Lindsay M Bearne, Prof John A Weinman

- | | Initial to
confirm |
|---|-------------------------------|
| 1. I confirm that I have read and understand the information sheet dated 15 July 2011 for the above study. | <input type="checkbox"/> |
| 2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | <input type="checkbox"/> |
| 3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. | <input type="checkbox"/> |
| 4. I understand that the interview will be audio recorded, and consent to it being documented and transcribed. | <input type="checkbox"/> |
| 5. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from King's College London, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. | <input type="checkbox"/> |
| 6. I agree to take part in the above research study. | <input type="checkbox"/> |

Name of participant

Signature

Date

Name of person taking consent

Signature

Date

Name of researcher

Signature

Date



Are patient beliefs associated with walking performance in PAD?

Participant Information Sheet (15 July 2011)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

Peripheral arterial disease (PAD) can cause leg pain or discomfort, which limits the ability to walk and carry out everyday activities. Walking exercise can lead to improvements, but it can also be painful, and people with PAD often have difficulty keeping up regular walking on their own. A better understanding of the experiences of people with PAD could help us develop programmes that motivate people to walk more and improve overall health. Therefore, the aim of this study is to determine if beliefs about illness and treatment held by people with PAD are associated with their ability to walk. We also hope to find out whether a brief questionnaire on beliefs about walking exercise is consistent over time in the results it provides.

Why have I been chosen?

You were invited to participate in this study because you have been diagnosed with PAD and experience symptoms of leg pain ('claudication') when you walk. We hope to include 202 participants with PAD in total. This study has been funded by the Dunhill Medical Trust, a registered UK charity.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. If you decide to take part you are still free to withdraw from the study at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

You will be asked to visit the Division of Health and Social Care Research (Guy's Campus, King's College London) for a session that will take approximately **90 minutes** in total. First, you will be asked to complete a 6 Minute Walking Test. This involves walking at a moderate pace (your breath is raised but you can still hold a conversation) for up to 6 minutes around a track. During the walk, you will be asked to indicate the point when you begin to feel leg pain. We will also record if you must stop walking due to leg pain, if this occurs before 6 minutes. Upon completion of the test you will be able to sit and recover for 30-45 minutes. During this time, you will be asked to complete a set of 6 questionnaires which ask you about your beliefs about your condition and walking as a treatment. You can choose not to respond to a question if you feel it is inappropriate. You will then be asked to repeat the 6 Minute Walking Test a second time.

In order to evaluate whether beliefs change over time, some participants will be given an envelope containing a brief questionnaire on beliefs about walking as a treatment for leg pain. If you receive this, you will be asked to take this home and, in one week's time, to complete the questionnaire, and return it to the researcher in a pre-paid stamped envelope.

What are the other possible disadvantages and risks of taking part?

A 6 minute walking test might cause leg pain, fatigue or discomfort. You will be asked to walk up to a moderate level of discomfort, but you may choose to terminate the walking test or withdraw from the study altogether at any point with no consequences. Completing questionnaires about your beliefs about PAD may be tiring, and may cause you to feel worried or anxious. However, you can choose not to respond to any questions you feel inappropriate. If you have concerns about any aspect of this study, you may contact the researchers who will do their best to answer your questions (contact Melissa Galea 0207 848 6679).

What are the possible benefits of taking part?

By completing the questionnaires, you may learn about your own thoughts and beliefs about PAD and walking as a treatment. The walking test will provide you information on your walking ability in a safe and secure environment. The information we get from this study may help us to develop a programme that aims to help people with PAD to walk more by targeting important beliefs. It may also help develop a suitable questionnaire for PAD patients on beliefs about walking exercise as a treatment.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without giving us a reason and we will destroy all your identifiable samples, but we would like to use the data (which will not be identifiable) collected up to your withdrawal in the final study analysis, if you do not object.

What if something goes wrong?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. Regardless of this, if you have concerns about any aspect of the way you have been approached or treated during the course of this study you may wish to contact the hospital's Patient Advice and Liaison Service (PALS) on 0207 188 8801.

What will happen to the information that is collected from the study?

Any information you provide during the course of the research and any information about you that leaves the hospital will be kept strictly confidential and anonymous and you will not be identified in any way by your responses to study questions. The results of the study will be published in medical journals and presented at medical conferences. Copies of the results can be obtained from the study organiser (Dr Lindsay Bearne) when the study is completed.

What happens now?

You will be contacted by the researcher (Melissa Galea) to discuss whether you would like to participate in this study. The researcher will be able to answer any questions you might still have about participating and an appointment made at a mutually convenient time.

Thank you for taking the time to learn more about this study. If you have any questions please contact:

Melissa Galea (0207 848 6679, melissa.galea@kcl.ac.uk)
Dr Lindsay M Bearne (0207 848 6322, Lindsay.bearne@kcl.ac.uk)
King's College London, Division of Health and Social Care Research
Guy's Campus, London, SE1 1UL

Appendix 1.5 Participant Consent Form for a cross-sectional observational study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD in people with IC



Are patient beliefs associated with walking performance in PAD?

Consent Form

Participant ID _____

Researchers: Melissa Galea, Dr Lindsay M Bearne, Prof John A Weinman

- | | Initial to
confirm |
|--|-------------------------------|
| 1. I confirm that I have read and understand the information sheet dated 15 July 2011 for the above study. | <input type="checkbox"/> |
| 2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | <input type="checkbox"/> |
| 3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. | <input type="checkbox"/> |
| 4. I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from King's College London, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. | <input type="checkbox"/> |
| 5. I agree to take part in the above research study | <input type="checkbox"/> |

Name of participant

Signature

Date

Name of person taking consent

Signature

Date

Name of researcher

Signature

Date

Appendix 1.6 Ethical approval notice for a feasibility and acceptability study of an RCT of a physiotherapist-led behaviour-change intervention targeting walking in people with IC


Health Research Authority
National Research Ethics Service
NRES Committee North West –Greater Manchester West
 3rd Floor
 Barlow House
 4 Minshull Street
 Manchester
 M1 3DZ
 Telephone: 0161 625 7434

18 February 2014

Dr Lindsay M Beame
 King's College London
 Academic Department of Physiotherapy
 3.6 Shepherd's House, Guy's Campus
 London
 SE1 1UL

Dear Dr Beame

Study title: A Psychological Intervention to Increase Walking in Patients with Intermittent Claudication: A Replication and Extension Pilot Study
REC reference: 14/NW/0089
IRAS project ID: 143466

Thank you for your email of 12 February 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 10 February 2014

Documents received

The documents received were as follows:

Document	Version	Date
Participant Consent Form: GSTT & KCH	2	12 February 2014
Participant Information Sheet: GSTT & KCH	2	12 February 2014

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Covering Letter	1	16 January 2014
Evidence of insurance or indemnity		01 August 2013
GP/Consultant Information Sheets	1 - GSTT & KCL	11 December 2013
Interview Schedules/Topic Guides	1 - Intervention Script	06 January 2014
Interview Schedules/Topic Guides	1 - Attention-control Script	06 December 2013
Investigator CV	Beame	

Investigator CV	Weinman	
Investigator CV	Galea Holmes	
Participant Consent Form: GSTT & KCH	2	12 February 2014
Participant Information Sheet: GSTT & KCH	2	12 February 2014
Protocol	1	18 January 2014
Questionnaire: Action Planning & Action Control - Intervention Group		
Questionnaire: Action Planning & Action Control - Control Group		
Questionnaire: Barrier self-Efficacy Questionnaire		
Questionnaire: Baltimore Activity Scale for Intermittent Claudication		
Questionnaire: Dietary Behaviour Questionnaire		
Questionnaire: Illness Perceptions Questionnaire		
Questionnaire: IPAQ		
Questionnaire: Theory of Planned Behaviour Questionnaire		
Questionnaire: SF-12v2		
Questionnaire: Demographic Questionnaire	1	13 November 2013
Questionnaire: Walking Consequences Questionnaire	1	13 November 2013
REC application	3.5	30 January 2014

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

14/NW/0089

Please quote this number on all correspondence

Yours sincerely



Anna Bannister
REC Manager

E-mail: nrescommittee.northwest-gmwest@nhs.net

Copy to: *Mr Keith Brennan, King's College London*
Mrs Karen Ignatian, Guy's and St Thomas' NHS Foundation Trust



Increasing Healthy Behaviour in People with Intermittent Claudication Participant Information Sheet (12 February 2014)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

Peripheral arterial disease (PAD) can cause leg pain or discomfort, which limits the ability to walk and carry out everyday activities. Lifestyle changes, like increasing walking exercise and enjoying a healthier diet, can lead to improvements, but can be a challenge to begin and then keep up over the long-term. The aim of this study is to learn if a psychological intervention can improve healthy behaviours and physical ability in people with PAD. The intervention is designed to build a positive understanding of PAD and healthy behaviours and help individuals with PAD develop strategies to adopt lifestyle changes. This study has been funded by the Dunhill Medical Trust, a registered UK charity.

Why have I been chosen?

You were invited to participate in this study because you have been diagnosed with PAD and experience symptoms of leg pain ('claudication') when you walk. We hope to include 24 participants with PAD in total.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. If you decide to take part you are still free to withdraw from the study at any time without giving a reason. Whether you agree or decline will not affect the standard of care you receive.

What will happen to me if I take part?

Your involvement in this study will last 4 months. First, you will be asked to visit King's College London, Guy's Campus, London Bridge) for a 90 minute appointment. You will be asked to complete a 6 minute walking test along a flat indoor surface. During the walk, you will be able to stop and rest at any point, to relieve any leg pain or if you are tired. You will then be able to sit and recover while you complete a set of questionnaires that ask about your beliefs about PAD, walking as a treatment and dietary behavior. Then, you will be given a pedometer, which is a small device you can wear on your waistband and which counts the steps you take. You will be asked to take the pedometer home with you and wear this during the day for the next 6 days. Over the next 2 weeks a physiotherapist will visit you in your home on two separate occasions, to pick up the pedometer and to discuss your beliefs about PAD and to set goals and plans for healthy lifestyle changes. These visits will last **60 min** and will take place at a time that is convenient for you. The physiotherapist will telephone you after 4 and then 8 weeks to see how you are getting on with your goals and to help you address any problems or challenges in achieving your goals. At the end of the study, you will be asked to visit King's College London for a second appointment where you will repeat the 6 Minute Walk Test, fill out a set of questionnaires and be given a pedometer to take home once again. You will also be given a postage paid envelope that you can

return the pedometer in once you are finished wearing it. You may be invited to volunteer and provide feedback on your experience of the intervention by telephone or a face to face interview which will take place at KCL or your home. The interview will last up to 45 minutes. Interviews will be audio recorded. The audio tapes will be transcribed then destroyed. Direct quotes from the interviews may be used in the write up of the study but these will be anonymised and not able to be traced back to the participant.

What are the possible disadvantages and risks of taking part?

A 6 minute walking test might cause leg pain, fatigue or discomfort. You will be asked to walk at a brisk pace, but will be able to stop and rest at any point during the 6 Minutes. Completing questionnaires about your beliefs and health behaviours may be tiring, and may cause you to feel worried or anxious. However, you can choose not to respond to any questions you feel are inappropriate. If you have concerns about any aspect of this study, you may contact the researchers (Melissa N Galea Holmes 0207 848 6679) who will do their best to answer your questions.

What are the possible benefits of taking part?

The physiotherapist visits will provide you with information about PAD and leg pain, and will help you build goals and plans to begin healthy lifestyle changes. By completing the questionnaires, you may learn about your own thoughts and beliefs about PAD and walking as a treatment. The 6 Minute Walk Test will provide information on your walking ability in a safe and secure environment. The information we get from this study will help us to develop a programme that aims to help people with PAD make healthy lifestyle changes.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without giving us a reason and we will remove any personal information, like your name and phone number, from our records. But we would like to use any anonymous data collected up to your withdrawal in the final study analysis, if you do not object.

What if something goes wrong?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. Regardless of this, if you have concerns about any aspect of the way you have been approached or treated during the course of this study you may wish to contact the hospital's Patient Advice and Liaison Service (PALS) on 0207 188 8801.

What will happen to the information that is collected from the study?

Any information you provide during the course of the research and any information about you that leaves the hospital will be kept strictly confidential and anonymous and you will not be identified in any way by your responses to study questions. The results of the study will be published in medical journals and presented at medical conferences. Copies of the results can be obtained from the researcher (Melissa Galea Holmes) when the study is completed. Copies of your signed consent form will be filed into your medical notes and a copy of this information letter will be sent to your GP to inform them that you have taken part in the study.

What happens now?

You will be contacted by the researcher (Melissa Galea Holmes) to discuss whether you would like to participate in this study. The researcher will be able to answer any questions you might still have about participating and an appointment made at a mutually convenient time. Thank you for taking the time to learn more about this study. If you have any questions please contact:

Melissa Galea (0207 848 6679, melissa.galea@kcl.ac.uk)
Dr Lindsay M Bearne (0207 848 6322, Lindsay.bearne@kcl.ac.uk)
King's College London, Division of Health and Social Care Research
Guy's Campus, London, SE1 1UL



Increasing Healthy Behaviour in People with Intermittent Claudication

Consent Form

Participant ID _____

Researchers: Melissa N Galea Holmes, Dr Lindsay M Bearne, Prof John A Weinman

- | | Initial to confirm |
|--|---------------------------|
| 6. I confirm that I have read and understand the information sheet dated 12 February 2014 for the above study. | <input type="checkbox"/> |
| 7. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | <input type="checkbox"/> |
| 8. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. | <input type="checkbox"/> |
| 9. I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from King's College London, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. | <input type="checkbox"/> |
| 10. I consent for my GP to be informed about my participation in this study | <input type="checkbox"/> |
| 11. I consent to phone calls and interviews to be audio recorded and that direct anonymised quotes may be used | <input type="checkbox"/> |
| 12. I agree to take part in the above research study | <input type="checkbox"/> |

Name of participant	Signature	Date
Name of person taking consent	Signature	Date

Appendix 1.9 Sample letter provided to General Practitioners informing them of patient participation in a feasibility and acceptability study of an RCT of a physiotherapist-led behaviour-change intervention targeting walking for people with IC



DD/MM/YY

Dear M _____,

**RE: Patient Participation in a Research
Study: Increasing Healthy Behaviour in People with Intermittent Claudication**

Patient name: _____
Address: _____

DOB: _____
NHS Number: _____

I am writing to inform you that your patient has been given information about a pilot intervention study which provides home-based support to increase healthy behaviours among individuals with intermittent claudication. [Patient Name] has met the inclusion criteria and has consented to take part. I enclose a copy of the participant information sheet.

The study is part of a PhD project that is sponsored by King's College London and Guy's & St Thomas' NHS Foundation Trust, and funded by the Dunhill Medical Trust (RTF 09/0110).

Walking exercise is an important treatment strategy for individuals with intermittent claudication and peripheral arterial disease. However, uptake and adherence to walking advice is poor, and patients report a desire for clearer instructions and better support in order to adopt this lifestyle change. This study randomizes participants to either an intervention group, which receives two 60 min sessions and follow-up telephone consultations with a physiotherapist, who will support individuals to adopt a regimen of walking, or an attention-control group, which receives the same contact time during which the physiotherapist will provide information on dietary changes. Participants in both groups will also attend two laboratory assessments where they will complete a 6 Minute Walk Test and questionnaires on beliefs about walking exercise, illness perceptions and attitudes toward pain. A subsample of participants will also be invited to attend an interview where they will be asked to remark on their experience of the intervention programme.

Should you have any questions regarding the study, or any concerns regarding your patient's participation, then please do not hesitate to contact us.

Yours sincerely,

Dr Lindsay Bearne, Principal Investigator
Mrs Melissa N Galea Holmes, PhD Investigator

King's College London
Division of Health and Social Care Research
Academic Department of Physiotherapy
3.11 Shepherd's House
Guy's Campus
London SE1 1UL
Tel: 0207 848 6679

Appendix 2

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Appendix 2.1 6MWT script

Have patient stand and rate their baseline pain intensity (CR10) and exertion (RPE).

"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able.

You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."

Demonstrate by walking one lap yourself. Walk and pivot around a cone briskly.

"Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog.

I would also like you to tell me when you begin to feel pain or discomfort in your legs."

"Start now, or whenever you are ready."

*During test, stand by the start line and do not walk with patient.
Visibly tick markers as patient completes a lap.*

5 minutes left: "You are doing well. You have 5 minutes to go."

4 minutes left: "Keep up the good work. You have 4 minutes left."

3 minutes left: "You are doing well. You are halfway done."

2 minutes left: "Keep up the good work. You only have 2 minutes left."

1 minutes left: "You are doing well. You only have 1 minutes to go."

15 s left: "In a moment, I'm going to tell you to stop. When I do, just stop right where you are and I will come to you."

0 minutes: "Stop!" (Take chair to patient; begin timing rest).

If patient stops walking during the test to rest: "You can lean against the wall or have a seat if you would like; then continue walking whenever you feel able."

Have patient stand and rate their post-test pain intensity (CR10) and exertion (RPE).

Appendix 2.2 6MWT worksheet

Date: _____	Patient ID _____
Walk # _____	Height: _____ metres
	Weight: _____ kg

Baseline exercise pain _____ (Borg CR10)
Baseline exercise exertion _____ (Borg RPE)

Lap counter: _____

Pain-Free Walking (if indicated by patient):

Time: _____
Number of laps: _____ (×60.96 meters)
Final partial lap: _____ meters
Total distance walked: _____ meters

Maximal Walking (if patient stopped during walk):

Time: _____
Number of laps: _____ (×60.96 meters)
Final partial lap: _____ meters
Total distance walked: _____ meters

6-Min Walk Distance

Number of laps: _____ (×60.96 meters)
Final partial lap: _____ meters
Total distance walked in 6 minutes: _____ meters

Post exercise pain _____ (Borg CR10)
Post exercise exertion _____ (Borg RPE)

Stopped or paused before 6 minutes? No Yes

Reason: _____

Describe symptoms at end of exercise: _____

Tech comments: _____

Please circle the appropriate letter (a, b, or c) that best describes your answer to each question.

1. How far can you walk before you feel pain in your leg?

- a. Less than 100 metres.
- b. Between 100 and 200 metres.
- c. More than 200 metres.

2. What happens when you feel the pain while you walk?

- a. Stop walking.
- b. Slow down.
- c. Continue walking at the same pace.

3. How often do you walk at a fast pace?

- a. Rarely / never.
- b. Sometimes.
- c. Frequently.

4. How often do you walk up and down stairs?

- a. Rarely / never.
- b. Sometimes.
- c. Frequently.

5. How often do you walk up and down hills?

- a. Rarely / never.
- b. Sometimes.
- c. Frequently.

Appendix 2.4 International Physical Activity Questionnaire (IPAQ)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

☐

No vigorous physical activities → **Skip to question 3**

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**.

Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

☐

No moderate physical activities → **Skip to question 5**

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → **Skip to question 7**

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

Appendix 2.5 Theory of Planned Behaviour (TPB) Questionnaire

Guidelines indicate that people with leg pain should complete **at least 30 minutes** of walking exercise on **3 or more days per week**, walking through the pain until it reaches a **moderate** level.

Walking for 30 minutes at once can be difficult, so this target can be met through several bouts of walking, each lasting **at least 10 minutes**. For example, you could walk for 10 minutes, stop and rest, walk another 10 minutes, and so on. Or you could walk for 15 minutes in the morning and 15 minutes later in the day.

We would now like to ask about your personal views on the recommended walking exercise. For each question, circle the number that best represents how you feel.

It is mostly up to me whether or not I do the recommended walking exercise.						
1	2	3	4	5	6	7
completely disagree			neither agree nor disagree			completely agree
Most people who are important to me think that I should do the recommended walking exercise.						
1	2	3	4	5	6	7
completely disagree			neither agree nor disagree			completely agree
For me to do the recommended walking exercise would be...						
1	2	3	4	5	6	7
wise		somewhat wise	neither wise nor foolish	somewhat foolish		foolish
I will do the recommended walking exercise.						
1	2	3	4	5	6	7
completely disagree			neither agree nor disagree			completely agree
If it were entirely up to me, I am confident that I would be able to do the recommended walking exercise.						
1	2	3	4	5	6	7
completely disagree			neither agree nor disagree			completely agree
For me to do the recommended walking exercise would be...						
1	2	3	4	5	6	7
unpleasant		somewhat unpleasant	neither	somewhat pleasant		pleasant

My spouse/significant other approves of me doing the recommended walking exercise (tick here if not applicable to you: <input type="checkbox"/>)						
1 completely disagree	2	3	4 neither agree nor disagree	5	6	7 completely agree
For me, doing the recommended walking exercise would be...						
1 extremely easy	2	3	4 neither easy nor difficult	5	6	7 extremely difficult
My goal is to do the recommended walking exercise.						
1 completely disagree	2	3	4 neither agree nor disagree	5	6	7 completely agree
For me, doing the recommended walking exercise would be...						
1 good	2	3 somewhat good	4 neither bad nor good	5 somewhat bad	6	7 bad
My medical practitioner thinks that I should do the recommended walking exercise.						
1 completely disagree	2	3	4 neither agree nor disagree	5	6	7 completely agree
Doing the recommended walking exercise would be...						
1 enjoyable	2	3	4 neither enjoyable nor unenjoyable	5	6	7 unenjoyable
My closest friend or family member (other than my spouse/significant other) approves of me doing the recommended walking exercise.						
1 completely disagree	2	3	4 neither agree nor disagree	5	6	7 completely agree
I intend to do the recommended walking exercise.						
1 completely disagree	2	3	4 neither agree nor disagree	5	6	7 completely agree

For me to do the recommended walking exercise would be...						
1 boring	2	3 somewhat boring	4 neither boring nor interesting	5 somewhat interesting	6	7 interesting
How much personal control do you believe you have over whether or not you do the recommended walking exercise?						
1 complete control	2	3	4	5	6	7 absolutely no control
How much do you feel that whether you do the recommended walking exercise is beyond your control?						
1 completely beyond my control	2	3	4	5	6	7 completely within my control
Do you plan to do the recommended walking exercise?						
1 definitely not	2	3	4	5	6	7 definitely so
For me to do the recommended walking exercise would be...						
1 stressful	2	3	4 neither stressful nor relaxing	5	6	7 relaxing
How confident are you that you will be able to do the recommended walking exercise?						
1 completely unsure	2	3	4	5	6	7 completely sure
For me to do the recommended walking exercise would be...						
1 harmful	2	3	4 neither harmful nor beneficial	5	6	7 beneficial
To what extent do you see yourself as being capable of doing the recommended walking exercise?						
1 extremely capable	2	3	4	5	6	7 extremely incapable
Doing the recommended walking exercise would be...						
1 useless	2	3	4 neither useless nor useful	5	6	7 useful

YOUR VIEWS ABOUT PERIPHERAL ARTERIAL DISEASE

Listed below are a number of symptoms that you may or may not have experienced since your diagnosis with peripheral arterial disease (PAD). Please indicate (by circling *Yes* or *No*) whether you have experienced any of these symptoms since developing PAD, and then whether you believe that these symptoms are related to your condition.

	I have experienced this symptom <i>since having PAD</i>.		This symptom is <i>related to my PAD</i>.	
Pain	Yes	No	Yes	No
Sore Throat	Yes	No	Yes	No
Nausea	Yes	No	Yes	No
Breathlessness	Yes	No	Yes	No
Weight Loss	Yes	No	Yes	No
Fatigue	Yes	No	Yes	No
Stiff Joints	Yes	No	Yes	No
Sore Eyes	Yes	No	Yes	No
Wheeziness	Yes	No	Yes	No
Headaches	Yes	No	Yes	No
Upset Stomach	Yes	No	Yes	No
Sleep Difficulties	Yes	No	Yes	No
Dizziness	Yes	No	Yes	No
Loss of Strength	Yes	No	Yes	No

We are interested in your own personal views of how you now see your current condition. Please indicate how much you agree or disagree with the following statements about your illness, that is, peripheral artery disease (PAD), by ticking the appropriate box.

VIEWS ABOUT YOUR PAD	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
PAD has major consequences on my life					
My PAD is likely to be permanent rather than temporary					
When I think about my PAD I get upset					
My PAD will pass quickly					
My PAD makes me feel angry					
My PAD is a serious condition					
My PAD symptoms come and go in cycles					
My PAD does not have much effect on my life					
My PAD strongly affects the way others see me					
I have the power to influence my PAD					
Having this PAD makes me feel anxious					
My PAD will last a short time					
What I do can determine whether my PAD gets better or worse					
My PAD has serious financial consequences					
I get depressed when I think about my PAD					
There is a lot which I can do to control my PAD symptoms					
I expect to have PAD for the rest of my life					
My PAD causes difficulties for those who are close to me					

VIEWS ABOUT YOUR PAD	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
I have a clear picture or understanding of my PAD					
Nothing I do will affect my PAD					
My PAD makes me feel afraid					
My walking exercise treatment can control my PAD					
There is nothing which can help my PAD					
My PAD will improve in time					
The course of my PAD depends on me					
I don't understand my PAD					
There is very little that can be done to improve my PAD					
My PAD will last for a long time					
My PAD is a mystery to me					
The negative effects of my PAD can be prevented (avoided) by my walking exercise treatment					
The symptoms of my PAD are puzzling to me					
I go through cycles in which my PAD gets better and worse					
My PAD doesn't make any sense to me					
My actions will have no effect on the outcome of my PAD					
My walking exercise treatment will be effective in curing my PAD					
My PAD does not worry me					
The symptoms of my PAD change a great deal from day to day					
My PAD is very unpredictable					

We are interested in what you consider may have been the cause of your PAD. People are very different, and there are no correct or incorrect answers to the questions below. We would like to know your own views about the factors that caused your PAD rather than what others, including doctors or family, may have suggested to you. Below is a list of possible causes for your PAD. Please indicate how much you agree or disagree that they were causes for you by ticking the appropriate box.

POSSIBLE CAUSES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
Stress or worry					
Hereditary - it runs in my family					
A germ or virus					
Diet or eating habits					
Chance or bad luck					
Poor medical care in my past					
Pollution in the environment					
My own behaviour					
My mental attitude e.g. thinking about life negatively					
Family problems or worries					
Overwork					
My emotional state e.g. feeling down, lonely, anxious, empty					
Ageing					
Alcohol					
Smoking					
Accident or injury					
My personality					
Altered immunity					

Please list in rank-order the three most important factors that you now believe caused your peripheral arterial disease. You may use any of the items from the questions above, or you may have additional ideas of your own.

The most important causes for me are:

1. _____
2. _____
3. _____

Appendix 2.7 Revised Illness Perception Questionnaire (IPQ-R)

Where 0 is ‘not at all confident’ and 10 is ‘extremely confident’, how confident are you that you can walk for at least 30 minutes, at least 3 times a week, walking until the claudication pain is almost unbearable, before resting, when:

	Not at all confident										Extremely confident
1. The weather is bad	0	1	2	3	4	5	6	7	8	9	10
2. The walk is uphill	0	1	2	3	4	5	6	7	8	9	10
3. You are on your own	0	1	2	3	4	5	6	7	8	9	10
4. You are with someone who walks quickly	0	1	2	3	4	5	6	7	8	9	10
5. There is a flight of steps	0	1	2	3	4	5	6	7	8	9	10
6. You are tired	0	1	2	3	4	5	6	7	8	9	10
7. There is nowhere to stop for a rest	0	1	2	3	4	5	6	7	8	9	10

Appendix 2.8 Action Planning and Action Control Questionnaires

For each question, circle the response that best applies to you:

I have made a detailed plan regarding...

	Not at all true	Hardly true	Moderately true	Exactly true
(a) when to do my walking exercise	1	2	3	4
(b) where to do my walking exercise	1	2	3	4
(c) how to do my walking exercise	1	2	3	4
(d) how often to do my walking exercise	1	2	3	4

During the last 3 months, I have...

	Not at all true	Hardly true	Moderately true	Exactly true
(a) constantly monitored myself to ensure I walked frequently enough	1	2	3	4
(b) tried to make sure that I walked for at least 30 minutes until I reached a moderate level of leg pain	1	2	3	4
(c) had my walking exercise plan often on my mind	1	2	3	4
(d) always been aware of my agreed walking action plan	1	2	3	4
(e) really tried to walk for exercise regularly	1	2	3	4
(f) tried my best to follow through with my walking action plan	1	2	3	4

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
	▼	▼	▼
a	<u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf		
	<input type="checkbox"/> 1	<input type="checkbox"/> 2
b	Climbing <u>several</u> flights of stairs		
	<input type="checkbox"/> 1	<input type="checkbox"/> 2

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

- a. Accomplished less than you would like ☐ 1 ☐ 2 ☐ 3 ☐ 4
- b. Were limited in the kind of work or other activities ☐ 1 ☐ 2 ☐ 3 ☐ 4

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

- a. Accomplished less than you would like ☐ 1 ☐ 2 ☐ 3 ☐ 4
- b. Did work or other activities less carefully than usual ☐ 1 ☐ 2 ☐ 3 ☐ 4

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

- a Have you felt calm and peaceful?..... ☐ 1 ☐ 2 ☐ 3 ☐ 4
- b Did you have a lot of energy?..... ☐ 1 ☐ 2 ☐ 3 ☐ 4
- c Have you felt downhearted and low?..... ☐ 1 ☐ 2 ☐ 3 ☐ 4

7. During the past 4 weeks, , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Thank you for completing these questions!

Appendix 2.10 San Diego Claudication Questionnaire (SDCQ)

The following questions relate to your leg symptoms. Please circle the appropriate number in response **for each leg**, right **R** and left **L**.

1. Do you get **pain, discomfort or numbness** in your legs when you walk?

<u>R</u>	<u>L</u>	
1	1	← Yes
2	2	← No

2. Does this pain ever begin when you are **standing still** or **sitting**?

<u>R</u>	<u>L</u>	
1	1	← Yes
2	2	← No

3. In what part of the leg or buttock do you feel it?

	<u>R</u>	<u>L</u>	
(A) Includes calf/calves	1	1	← Yes
	2	2	← No
(B) Includes thigh/thighs	1	1	← Yes
	2	2	← No
(C) Includes buttock/buttocks	1	1	← Yes
	2	2	← No

4. Do you get it when you **walk uphill or hurry**?

<u>R</u>	<u>L</u>	
1	1	← Yes
2	2	← No
3	3	← Never walk uphill or hurry

5. Do you get it if you walk at an **ordinary pace** on the level?

<u>R</u>	<u>L</u>	
1	1	← Yes
2	2	← No

6. Does the pain ever **disappear** while you are **still walking**?

<u>R</u>	<u>L</u>	
1	1	← Yes
2	2	← No

7. **What do you do** if you get this pain while you are walking?

<u>R</u>	<u>L</u>	
1	1	← Stop or slow down
2	2	← Carry on

8. What happens to it if you **stand still**?

<u>R</u>	<u>L</u>	
1	1	← Lessens or relieved
2	2	← Unchanged

(A) If it is lessened or relieved, **how soon**?

<u>R</u>	<u>L</u>	
1	1	← 10 minutes or less
2	2	← More than 10 minutes

Appendix 2.11 Borg Category–Ratio 10 Scale for Pain (CR10)

Instructions: Think of the three worst experiences of pain you have ever had. If you use 10 on the following scale as the worst pain you have ever experienced or can think of, how would you rate the **intensity** of pain or discomfort in your legs when you stopped walking?

Start by looking at the *verbal expressions* and then chose a *number*. For example, if your pain was “Very slight,” chose 1, if “Moderate,” chose 3, and so on. You can also use half values (such as 1.5, 3.5 or decimals such as 0.4, 0.8, or 2.3).

0	Nothing at all
0.5	Just noticeable
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	Very, very severe
10	Maximal

Appendix 2.12 Borg Rating of Perceived Exertion (RPE)

Instructions: While exercising we want you to rate your perception of exertion, that is, how heavy and strenuous the exercise feels to you. The perception of exertion depends mainly on the strain and fatigue in your muscles and on your feeling of breathlessness or aches in the chest.

Look at this rating scale; we want you to use this scale from 6 to 20, where 6 means 'no exertion at all' and 20 means 'maximal exertion'. Try to appraise your feeling of exertion as honestly as possible, without thinking about what the actual physical load is. Look at the scale and the expressions and then give a number.

6	No exertion at all
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard (heavy)
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion

Appendix 3

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Appendix 3.1 A representative search strategy conducted in Medline within the Ovid interface for a systematic review evaluating behaviour-change techniques targeting walking in individuals with IC

intermittent claudication.mp. or Intermittent Claudication/
peripheral vascular disease.mp. or Peripheral Vascular Diseases/
peripheral arterial disease.mp.
Arterial Occlusive Diseases/ or peripheral arterial occlusive disease.mp.
claudication.mp.
("peripheral arterial disease" or "peripheral vascular disease" or "peripheral arterial occlusive disease" or "claudication" or "peripheral occlusive arterial disease").ab,ti.
Attitude/ or attitude.mp.
self-efficacy.mp. or Self Efficacy/
"behavior and behavior mechanisms"/ or psychological theory/ or psychology, applied/
Cognition/ or cognition.mp.
Beliefs/
motivation.mp. or Motivation/
Intention/ or intention.mp.
Cognitive Therapy/ or Behavior Therapy/
intervention.mp. or Intervention Studies/
(attitud* or cognit* or belief* or percei* or percep* or "self ADJ efficacy" or "self-efficacy" or intention* or motivat*).ab,ti.
Walking/ or walking.mp.
exercise.mp. or Exercise/ or Exercise Therapy/
"physical activity".mp.
(walk* OR exercise* or "physical activity").ab,ti

Search terms reflect the disease, psychological interventions or variables, and outcome. ab,ti, abstract or title; mp, keyword; /, subject heading.

Appendix 3.2 Full text screening criteria for a systematic review evaluating behaviour-change techniques targeting walking in individuals with IC

Step	Criterion	Description	Action
Study design^a			
A	Is the study an experimental design?	Include a) RCTs; b) Quasi-randomised trials; c) non-randomised/quasi-experimental trials (e.g., allocation by patient/physician preference); or d) protocol report of any of the above designs.	Yes: answer E No: answer B
B	Is the study an observational design in which participants receive an intervention?	Include a) controlled before-and-after study; b) concurrent cohort study; c) historical cohort study; d) case-control study; or e) before-and-after study.	Yes: answer E No: answer C
C	Is the study a non-intervention design?	Include a) cross-sectional design; and b) prospective observational studies.	Yes: answer F No: answer D
D	Is the study a qualitative design?	Include a) individual interview; and b) focus group studies.	Yes: answer H No: exclude
Study methods			
E	Does the treatment arm receive a behaviour-change intervention?	See Michie et al (2011). Intervention can include any behaviour-change strategy and can be provided in isolation or in adjunct to an exercise training programme.	Yes: answer G No: exclude
F	Are psychosocial variables included as a determinant?		Yes: answer G No: exclude
G	Is either walking behaviour or walking ability included as an outcome measure?	Can be the primary or secondary outcome. Walking behaviour includes regular walking activity assessed by an objective (e.g., pedometer) or validated subjective (e.g., PASE) measure. Walking ability includes functional walking performance assessed by a validated method (e.g., 6 Minute Walk Test, Shuttle Walk Test, graded treadmill test), and may include measures of pain-free or maximal walking ability.	Yes: Include No: exclude
H	Does the qualitative study describe patient beliefs that could influence walking behaviour or ability?		Yes: Include No: exclude

^aStudy designs other than randomised controlled trials were retrieved for the purpose of reviewing the literature for this thesis, but were excluded from the systematic review.

Appendix 3.3 Data extraction tool applied to a study included in a systematic review evaluating behaviour-change techniques targeting walking in people with IC

Outcome	Extracted data
Author (date)	Collins et al. 2011
Study code:	029
Study design:	RCT
Method of randomisation:	Permuted blocks with block sizes 2, 4, 6 or 8
Concealment of allocation:	Yes
Blinded:	No <input type="checkbox"/> Single X Double <input type="checkbox"/> Triple <input type="checkbox"/> Unclear <input type="checkbox"/> NA <input type="checkbox"/>
<i>A priori</i> power calculation:	Yes
Total number of patients randomised/enrolled:	n=145
• Number identified/screened:	n=1756
• Number eligible:	n=145 (same as number randomised)
• Number refused before randomisation:	NR
• Number excluded before randomisation	n=1611 (1294 + 317)
Notes:	Two stages of screening (telephone and in-person), no refusals pre-randomisation.
Number included in follow-up 1:	3 months, n=145
Number included in follow-up 2 (if applicable):	6 months, n=126
Number included in follow-up 3 (if applicable):	NA
Attrition rate at final follow-up	13.1%
Attendance/compliance, %	NR
“Intention to treat” analysis:	Yes
Source of funding:	Not stated <input type="checkbox"/> Pharmaceutical <input type="checkbox"/> Other X
Description of funding source:	American Diabetes Association
Country:	USA
Setting/Location:	Home-based, some sessions at a walking centre.
Number of centres:	Single-centre
Description:	IC and type I or II DM
Number:	145
Age:	66.5 years (SD 10.1)
Sex:	Female n=45 (31%); Male n=100 (69%)
Baseline ankle–brachial pressure index:	Control: mean 0.94 (SD 0.45), Intervention: mean 0.96 (SD 0.38).

Baseline maximal walking ability:	Mean 448 metres (SD 237.1)
Baseline pain-free walking ability:	Control: mean 166.1 metres (SD 169.6), Intervention: mean 149.1 metres (SD 147.0).
Other:	Baseline vasodilator use: Control n=19/73 (26%), Intervention n=6/72 (8%)
Inclusion criteria:	Men/women aged >40 years, diagnosed with PAD (resting ABI<0.90, TBI≤0.70, or surgery for PAD), type I or II DM, exertional leg symptoms
Exclusion criteria:	No intention to start exercising in next 6 months (i.e., pre-contemplators based on PAR-Q), no available phone, foot/lower leg amputation, CLI, lower extremity revascularisation <6 months before enrolment, MI <3 months before enrolment, significant coronary ischemia at low workload (treadmill test), systolic BP>180 mmHg or diastolic blood pressure >110 mmHg, diagnosis of life-threatening malignancy within past year, exercise tolerance limited by comorbid condition.
Description of treatment(s):	Home-based exercise programme with weekly group training sessions
Duration	6 months. Advice to walk 50 minutes/session. Advice to increase pedometer walking by 50 steps/session.
Frequency of sessions:	4 days/week (1 with group and 3 at home)
Type/mode of exercise:	Walking, cycling, stretching, strength training.
Intensity of exercise/pain threshold:	NR
Behaviour change component:	Home-based walking programme: <ol style="list-style-type: none"> 1) Baseline one-on-one interaction with research coordinator guided by the PACE instrument: discussion on current stage of change (based on response to modified PACE part 1), and discussion of patient responses to relevant PACE part 2. 2) Two 1-hour walking exercise sessions led by an experienced exercise instructor. "Served as reinforcement and facilitated treatment adherence." Session 1: Group session designed to facilitate interaction among participants. Instructor asked participants to describe what they hoped to gain from walking exercise. Group discussion of strategies for staying in the walking programme. Session 1: Practice walking session with one or more participants. Patients listened to an audiotaped instructional aid (AHA), then instructed on home walking and encouraged to attend weekly group walking class. 3) Biweekly telephone calls for 6 months. Participants completed the PACE assessment and Exercise Behaviour Questionnaire (i.e., Stanford Patient Education Research Centre Exercise Behaviour Survey), discussed strategies for risk factor control and adherence to walking during past 2 weeks.
Adverse events:	Assessed, but none reported by participants.
Control/placebo (brief description of treatment):	Attention control: Participants received twice-monthly phone calls with the research coordinator. Duration 10-15 min. Participants shared and discussed the information documented in calendars (see standard care) on blood glucose, BP, cholesterol, and smoking habits as applicable. The Exercise Behaviour Questionnaire (i.e., Stanford Patient Education Research Centre Exercise Behaviour Survey) was administered.

Outcome		Description/ measure used	Time points	n	Results		
Maximal walking ability		Gardner-Skinner graded exercise treadmill test.	Baseline	Intervention n=72 Control n=73	Mean 422.7 metres (SD 234.2)	Mean 472.6 metres (SD 238.9)	p=0.208
			3 months	NR	NR	NR	
			6 months	Intervention n=61 Control n=65	Mean Δ 24.5 (SD 19.6)	Mean Δ 39.2 (SD 19.6)	p=0.598
Pain-free walking ability		Gardner-Skinner graded exercise treadmill test.	Baseline	Intervention n=72 Control n=73	Mean 149.1 (SD 147)	Mean 166.1 (SD 169.6)	p=0.522
			3 months	NR	NR	NR	
			6 months	NR	Mean Δ 66.7 (SD 21.0)	Mean Δ 52.3 (SD 23.6)	NR
Walking behaviour		NA	Other:	NA	NA	NA	NA
			Baseline	NA	NA	NA	NA
			3 months	NA	NA	NA	NA
Self-reported walking ability		NA	NA	NA	NA	NA	NA
Notes		Attention control was not equivalent in frequency/duration of attention as the intervention group (e.g., bimonthly calls versus biweekly calls). Although secondary outcomes were 3 month change in key parameters, no 3 month data was reported.					
Downs & Black score	Reporting (max 11): 10	External validity (max 3): 1	Internal validity – bias (max 7): 5	Internal validity – confounding (max 6): 5	Power (max 5): 0	Total score (max 27): 21	
Cochrane score: Is risk of bias evident?	Random sequence generation: Y	Allocation concealment: Y	Blinding of participants/ personnel: Y	Blinding of outcome assessment: Y	Incomplete outcome data: N	Selective Reporting: Y	Other sources of bias: N

AHA, American Heart Association; CLI, critical limb ischaemia; N, no; NA, not applicable; NR, not reported; PACE, PATient-Centred assessment and Counselling for Exercise; PAR-Q, Physical Activity Readiness Questionnaire; SD, standard deviation; Y, yes.

Appendix 3.4 Data extracted from studies included in a systematic review evaluating behaviour-change techniques targeting walking in individuals with IC

First author	Outcome				
	Maximal Walking Ability	Pain-Free Walking Ability	Self-reported walking ability		Daily walking behaviour
			Distance	Speed	
Cunningham (2010)	–	–	–		5274 ±3022 steps versus 3599 ±2850 steps ; p<0.001
Gardner (2011)	Δ124 ±193 seconds versus -10 ±176 seconds; p<0.05	Δ134 ±197 seconds versus -16 ±125 seconds; p<0.05	Δ10 ±25 versus 1 ±34; p=NS	Δ11 ±22 versus 4 ±25; p=NS	Δ3 ±76 min/day versus 4 ± 81 minutes/day; p=NS
Cheetham (2004)	Median 304 metres versus 175 metres; p<0.001	–	–		–
Christman (2003)	8 ±6 minutes versus 12 ±6 minutes; p=NS	5 ±4 minutes versus 7 ±5 minutes; p=NS.	–		–
Collins (2011)	Δ25 ±166 metres versus 39 ±168 metres; p=0.598 ^a	Δ67 ±178 metres versus 52 ±202 metres; p=0.651 ^a	Δ 6 ±30 versus 1 ±28; p=0.383 ^a	Δ6 ±19 versus -2 ±24; p=0.034 ^a	–
Quirk (2012)	–	–	–	–	Median (IQR) 330 MET-minutes/week (0–1238) versus 396 (0–1980); p=0.735.

Data are presented as intervention versus control and represent mean ±standard deviation (SD) unless indicated otherwise. ^aSD derived from data published as standard errors. NS, non-significant.

Appendix 4

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Appendix 4.1 Questionnaire assessing demographic and clinical characteristics of participants in a qualitative study exploring the experiences of and beliefs about walking in people with IC

Please complete all questions to the best of your ability.

Age: _____

Gender: ☐ Male ☐ Female

What is your marital or same-sex civil partnership status?

- ☐ Never married or in a same-sex civil partnership
- ☐ Married or in a same-sex civil partnership
- ☐ Separated, but still legally married or in a same-sex civil partnership
- ☐ Divorced or formerly in a same-sex civil partnership
- ☐ Widowed or a surviving partner of a same-sex civil partnership

Which of the following best describes your ethnic group or background?

White

- ☐ English/Welsh/Scottish/
Northern Irish/British
- ☐ Irish
- ☐ Gypsy or Irish Traveller

**Mixed/multiple ethnic
background**

- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian

Asian/Asian British

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Chinese

**Black/African/
Caribbean/Black British**

- ☐ African
- ☐ Caribbean

Other ethnic group

- ☐ Arab
- ☐ Any other ethnic group
(write in) _____

Smoking history (check the box that best applies to you):

- ☐ I am currently a cigarette smoker
- ☐ I used to smoke, but have NOT smoked a cigarette in the past 6 months
- ☐ I have never been a cigarette smoker

Are you, or have you ever been, diagnosed with:

- | | |
|------------------------|--|
| Diabetes mellitus | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Cholesterol | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| High blood pressure | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Cardiovascular disease | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Renal disease | Yes <input type="checkbox"/> No <input type="checkbox"/> |

Have you ever experienced a:

- | | |
|--------------|--|
| Heart attack | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Stroke | Yes <input type="checkbox"/> No <input type="checkbox"/> |

The following questions relate to the symptoms of pain or discomfort in your legs. Please answer each question to the best of your ability.

1. Which leg causes you the most severe **pain** or **discomfort** while you are walking?

- ☐ **Right** leg ☐ **Left** leg ☐ **Both** are the same ☐ Neither

2. Approximately how long have you been experiencing this **pain** or **discomfort**?

- ☐ Less than one year
☐ One to two years
☐ Greater than two years

3. Where do you get this pain or discomfort? Mark the place(s) with “x” on the diagram below.



4. Are you on any medication which helps to treat or alleviate the **pain** or **discomfort** that you experience in your legs during walking?

- ☐ Yes ☐ No

5. Do you have pain or discomfort caused by a condition other than the circulation in your legs (e.g. foot or back pain, arthritis, knee injury, etc.) that affects your ability to walk?

- ☐ Yes ☐ No

If you answered, “Yes”, please write down what this condition is here:

Appendix 4.2 Walking subscale of the Physical Activity Scale for the Elderly (PASE) used to evaluating walking behaviour among participants with IC in a qualitative study exploring experiences of and beliefs about walking

The following question is about how much walking you do.
Please circle the responses that best describes your walking activity.

1. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0.] NEVER	[1.] SELDOM	[2.] SOMETIMES	[3.] OFTEN
↓	(1–2 DAYS)	(3–4 DAYS)	(5–7 DAYS)
Skip 1a.	↓	↓	↓

1a. On average, how many hours per day did you spend walking?

[1.] LESS THAN 1 HOUR	[2.] 1 BUT LESS THAN 2 HOURS
[3.] 2–4 HOURS	[4.] MORE THAN 4 HOURS

Appendix 4.3 Sample of transcribed data, field notes, and reflexive analysis of an interview with one participant in a qualitative study exploring experiences of and beliefs about walking for IC

MG: Can you tell me about your condition?

128B: My condition, em, was first diagnosed, em, at [Name of Hospital], and I had an angiogram, um, with the dye test, and, um they was – were – going to do the angioplasty, but then I was referred onto Mr [Name of Consultant], em, who, em, in turn carried out the procedure of the balloon procedure. Had that not have been a success I was going to have the stent. If that failed, I was going to have the bypass. But fortunately at the time, the balloon procedure was a success, for a short while only unfortunately. And then I was referred back and I had a further, um, er, um, er [slaps knee and bites bottom lip, trying to think of the correct word] test in November, which revealed, yes it was beginning to, the vessels were beginning to narrow again. Um, and I have an appointment now, waiting to go back to see Mr [Name of Consultant] from that day in November.

MG: And what do you expect from that next appointment?

128B: The next appointment? Um, it remains to be seen at this stage, because, meanwhile, I've been referred to the cardiac department, and Mr [Name of Consultant] was aware of that, and um, when I saw him in November he felt that it was wise to wait for the result of any tests that were carried out in the cardiac department before proceeding with the, um, vascular procedure – any vascular procedure that might have to take place.

MG: And what are your thoughts on that?

128B: Well, at this stage, since November, seeing Mr [Name of Consultant], I am still, um, persevering with my walking, um, in the hope that, um, the vessels, will, um, work for themselves, in other words, try not to have any further procedure if that's possible. Um, at the same time, I know that I can, um, have the, well, I would have to have the stent if I could not succeed in getting the vessels working on their own through exercise.

MG: And how do you feel about that possibility?

128B: The stent?

MG: Mmm. [Yes]

128B: Well, so be it. Um, what is to be, will be. If I have to have the stent, then, you know, if it's going to answer the problem, in the long term, then, um, that's the road, you know, the avenue which we'll have to take.

MG: So, from that experience, how has that left you feeling about your condition?

128B: Very mindful, of course, of any, you know, life – any life-threatening condition that could be. I realise more than ever that I can't take it for granted, um, my health. And that I, I have to remain positive, and work toward, as far as possible, in trying to maintain and, um, if it has to be, correct the condition.

MG: You mentioned that you're concerned about life-threatening possibilities. Um, can you explain that further to me?

128B: Well, obviously, I have got, um, a cardiovascular condition as well. And um, it seems that um, I'm prime candidate for any, you know, um, setback, as far as having, um, heart attacks, or any, anything resulting from my present condition. Um, I'm very aware, for example, of trying to avoid contracting diabetes, and, whatever else you know it could cause, the condition I have.

MG: The condition being...?

128B: The blocked arteries.

MG: In the...? [pauses waiting for response]

128B: Yes, in the legs, the legs in particular. Because I realise that is the part of my body which we're working on.

MG: So, you've sort of described a number of different problems that you're faced with at the moment. Do you think they are linked?

128B: Um, the cardio and the vascular, the leg? Um, I really don't know? I presume in some way, they must because it's my body and, you know, the blockage is in my leg, and there appears to be some obstruction, um, calcium, in my um, arteries [pointing to chest], so you know, that being the case, it must be throughout my system somehow or another, so you know, I'm mindful of that.

MG: How do you feel about your health in general right now?

128B: Um, [smirks and points to wrist in a cast, rolling eyes], in general, well, mentally, I struggle to behave, to maintain a positive outlook. Um physically, um, I'm very conscious of movement, of keeping the body moving, and exercise and walking, and - apart from evening times of course, when I do relax and then fall asleep – but otherwise, throughout the day, for example hovering, housework general, and of course when the weather permits, gardening as a form of exercise. I'm fortunate enough to have a staircase that I'm up and down all day when I'm in the house, which I see as another form of exercise.

MG: So, why is this so important to you, the movement?

128B: Well, because I know it goes hand in hand with the condition that I have, and that it's going to improve my condition. Well, it's certainly not going to hinder it, you know, the more exercise I can carry out on a daily basis, um, it surely is the answer to helping to correct to some extent my condition.

MG: And what has been your experience of that so far?

128B: Of exercise? Um, yes, as a matter of fact, I find sometimes, walking the first 150 yards, after that it can be a bit of a struggle, but the more I persevere, the longer I walk, it seems to help overcome that pain that I experience in my calf, like a cramp experience. And the more I keep moving and have movement throughout my body, whatever I do, walking or any form of exercise, it is stimulating – it helps to stimulate the body. There's no two ways about it, you

know, you hear people who do all sorts of running and athletes and all sorts, you know, without overdoing it, they feel refreshed. And I feel somewhat the same in my small way of what I can do.

MG: And what is it like then to go for a walk? Can you tell me a bit more about that?

128B: Well, mentally and physically, it's um, it's uplifting. If for example I have no reason to go out, for example, one day last week, it was beautiful the weather, so I just went for a walk, not for any particular reason, but just to go for a walk, to get the exercise. I was out for about 30 min, 20 to 30 min, walking in my local area, not in parkland, but you know, where I live, and I did feel, you know, refreshed from doing that. And I felt that it was worthwhile, you know, um, and sometimes, um I will walk up to my local newsagent at [Street Name] to buy my weekly paper, or in the other direction to another newsagent which is 20, 25, 30 minutes way and back again, and sometimes to my local village, [Street Name], and then perhaps I will get the bus home after doing a bit of shopping, but not weather permitting of course again, I don't go out, of course when it's tipping down. [End of excerpt]

Field notes

This interview was conducted in the participant's home. Participant 128B had an unsuccessful angioplasty approximately 1 year ago. She is proactive in her health and well-being, and believes movement is essential. She actively manages her health through walking, diet and general activity and quit smoking last year after noticing a patient who had undergone amputation outside the hospital. She experiences anxiety and has had a stressful past following the loss of her son, and believes this is crucial to her health and finds ways to manage it through relaxation and humour. She feels she is responsible for her health and in control of the progress of her condition, and hopeful that she can improve her leg circulation or at least prevent it getting worse through lifestyle changes.

Reflexive diary

A good rapport was established quickly with the participant, who was very welcoming, open, and interested in getting to know the investigator (e.g., the participant asked the investigator questions about her professional work and personal life, and a conversation was easily initiated). The interview took place at the participant's home, and the investigator was made to feel welcome, and treated as a warm guest (e.g., offered tea and cake). The participant was sharp with a sense of humour, which made the interview overall enjoyable for the investigator. The participant was also very candid and open in sharing her thoughts and feelings, and was also articulate and thoughtful in her responses, so probing was minimal and the investigator was able to allow the interview to flow naturally from the participant's dialogue. The participant discussed her family extensively during the interview, including her deceased husband and son, pointing to family photos around the house, where relevant. She described her children as approximately the age of the investigator, and it may be that she was reminded of her family by the investigator's age, gender, appearance or other qualities. At times, the participant became quite emotional, when describing her family life and her condition; this was unexpected, but not awkward or uncomfortable, possibly as a good rapport had been established early on.

Appendix 5

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Appendix 5.1 Self-report assessment of sociodemographic and clinical characteristics of participants with IC in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD

Please complete all questions to the best of your ability.

Age: _____

Gender: ☐ Male ☐ Female

What is your marital or same-sex civil partnership status?

- ☐ Never married
- ☐ Married
- ☐ Separated, but still legally married
- ☐ Divorced
- ☐ Widowed

Which of the following best describes your ethnic group or background?

- ☐ White
- ☐ Asian/Asian British
- ☐ Black/African/Caribbean/Black British
- ☐ Mixed/multiple ethnic background
- ☐ Other ethnic group (please specify: _____)

Smoking history (check the box that best applies to you):

- ☐ I am currently a cigarette smoker
- ☐ I have quit or cut down on smoking within the past 6 months
- ☐ I used to smoke, but have not smoked a cigarette for at least 6 months
- ☐ I have never been a cigarette smoker

Are you, or have you ever been, diagnosed with:

Diabetes mellitus	Yes <input type="checkbox"/> No <input type="checkbox"/>
Cholesterol	Yes <input type="checkbox"/> No <input type="checkbox"/>
High blood pressure	Yes <input type="checkbox"/> No <input type="checkbox"/>
Cardiovascular disease	Yes <input type="checkbox"/> No <input type="checkbox"/>
Kidney disease	Yes <input type="checkbox"/> No <input type="checkbox"/>

Have you ever experienced a:

Heart attack	Yes <input type="checkbox"/> No <input type="checkbox"/>
Stroke	Yes <input type="checkbox"/> No <input type="checkbox"/>

Are you on any medication which helps to treat or alleviate the **pain** or **discomfort** that you experience in your legs during walking?

Yes ☐ No ☐

For how long have you had pain or discomfort in your legs when walking that is due to poor circulation?

- ☐ <1 year
- ☐ 1 – 2 years
- ☐ >2 years

Do you have pain or discomfort caused by a condition other than the circulation in your legs (e.g. foot or back pain, arthritis, knee injury, etc.) that affects your ability to walk?

Yes ☐ No ☐

If you answered, "Yes", write down what this condition is here: _____

Appendix 5.2 Patterns and rates of missing data across variables among 29 participants with IC who had incomplete data in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD

Variable	MDR, %	Participant																												
		59	68	71	72	91	52	19	74	107	134	32	106	135	142	20	34	46	82	99	111	141	51	28	63	76	86	94	100	128
Past behaviour ^a	0																													
TPB																														
Attitude	0																													
SN	3.4	•	•	•	•	•																								
PBC	0.7						•																							
CSM																														
Intention	0																													
Identity	0																													
Coherence	0.7							•																						
Personal control	2.1	•							•	•																				
Treatment control	0.7										•																			
Acute TL	0.7								•																					
Chronic TL	0																													
Consequences	0.7								•																					
Emotion	0.7											•																		
CA																														
Risk Factors	2.1												•	•	•															
Psychological	5.5						•									•	•	•	•	•	•	•								
Accident / chance	0.7																						•							
Immunity	4.8																							•	•	•	•	•	•	•
6MWD																														

^aItem 5 on the International Physical Activity Questionnaire. CA, causal attributions; Con, control; CSM, Common Sense Model; PBC, perceived behavioural control; SN, subjective norm; TL, timeline; TPB, Theory of Planned Behaviour; 6MWD, 6 Minute Walk Distance.

Appendix 5.3 Frequencies of reported causal attributions among participants with IC in a cross-sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD

Causal attribution	n/total n	Frequency, %
Smoking	96/145	66.2
Ageing	94/145	64.0
My own behaviour	65/144	45.1
Diet or eating habits	56/145	38.6
Alcohol	42/144	29.2
Stress	38/145	26.2
Heredity	36/144	25.0
Chance or bad luck	30/144	20.9
My emotional state	29/145	20.0
Overwork	21/144	14.6
Mental attitude	20/145	13.8
Family problems or worries	19/143	13.3
Poor medical care in my past	17/145	11.8
Accident or injury	16/145	11.0
Pollution	15/143	10.5
Altered immunity	9/141	6.4
My personality	8/140	5.7
Germ or virus	5/144	3.5

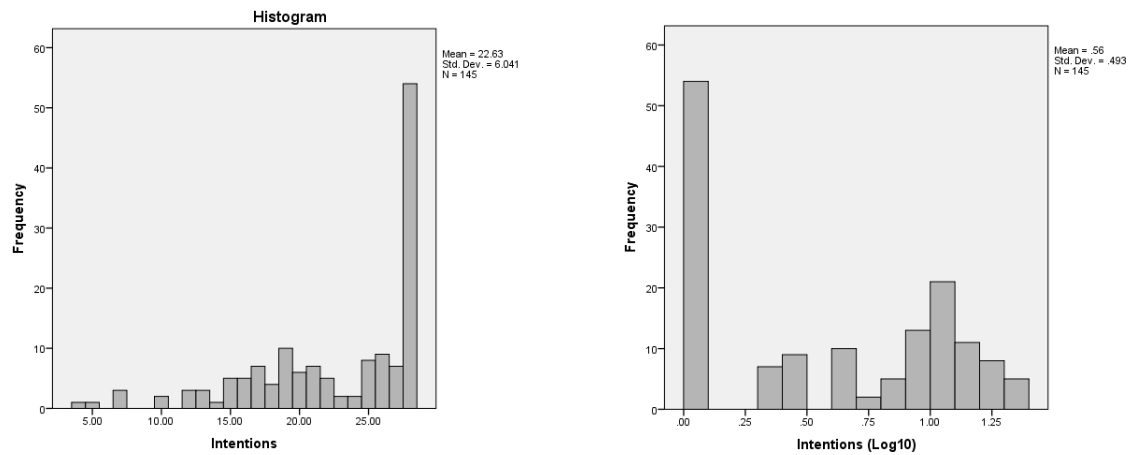
Responses of 'agree' or 'strongly agree' were defined as affirmative responses of a causal attribution. Total n reflects the number of valid responses (excluding missing data).

Appendix 5.4 Skewness and kurtosis values for independent and dependent variables in the cross sectional study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD

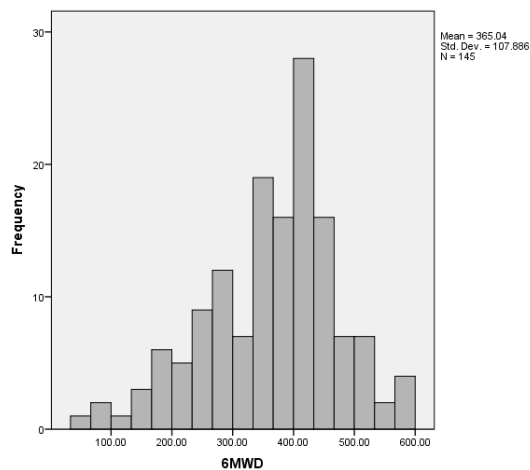
Variable	Skewness	Kurtosis
6MWD	-0.487	0.40
Intention	-0.985 ^a	0.212
Past walking behaviour	-0.552 ^a	-1.223 ^a
Attitude	-0.166	-0.325
Subjective norm	-0.682 ^a	-0.235
Perceived behavioural control	-0.400	-0.438
Identity	1.217 ^a	1.740 ^a
Coherence	-0.162	-0.601
Consequences	-0.097	0.124
Personal control	-0.365	0.795 ^a
Treatment control	-0.171	0.593
Acute timeline	0.063	-0.367
Cyclical timeline	0.069	-0.472
Emotional representation	0.119	-0.532
Psychological attributions	0.398	0.075
Risk factor attributions	-0.236	0.120
Immunity attributions	0.129	-0.425
Accident/chance attributions	0.482a	0.250

^aDepartures from normality

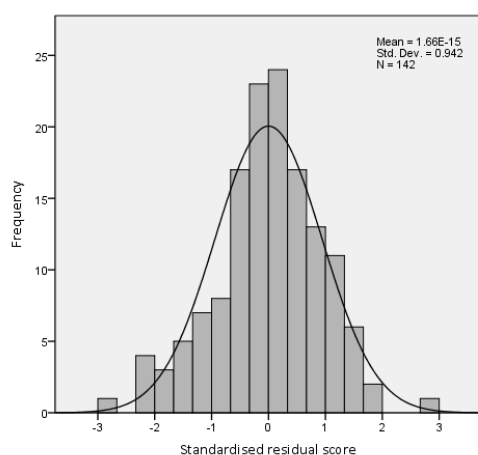
Appendix 5.5 Histogram illustrating the distribution of walking intention scores before and after reflection and log transformation in a cross-sectional observational study evaluating walking treatment and illness cognitions as determinants of walking intention and 6MWD



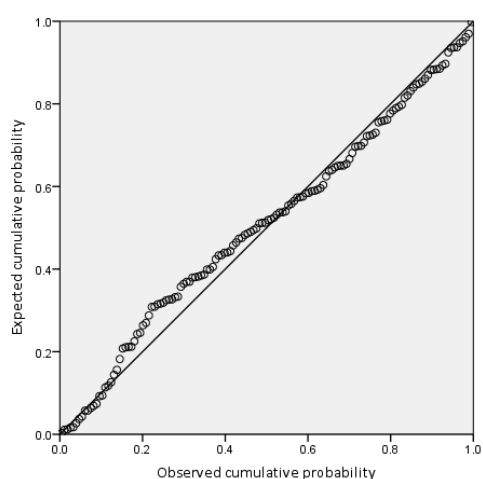
Appendix 5.6 Histogram illustrating the distribution of 6 Minute Walk Distance (6MWD) scores in a cross-sectional observational study evaluating walking treatment cognitions and illness cognitions as determinants of walking intention and 6MWD



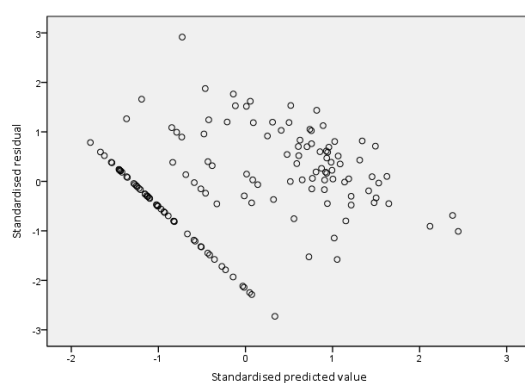
Appendix 5.7 Histogram of the frequencies of standardised residual scores for a hierarchical multiple linear regression evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of walking intention



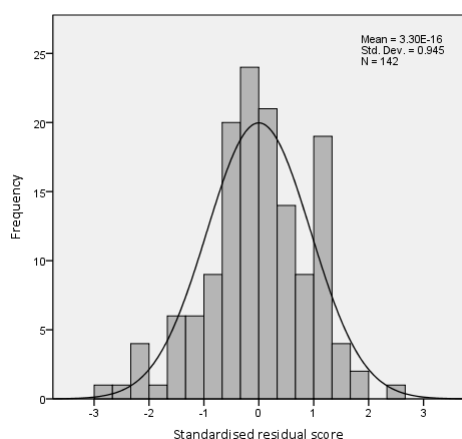
Appendix 5.8 Normal P-P plot of standardised residual scores for a hierarchical multiple linear regression evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of walking intention



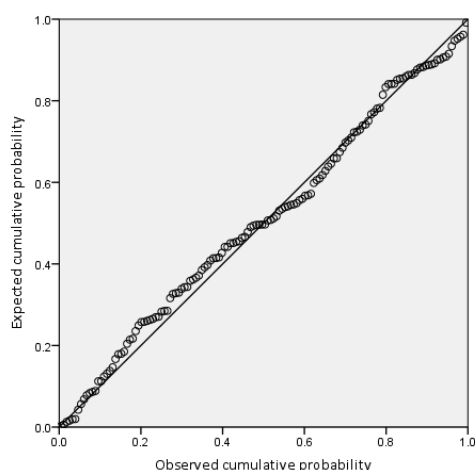
Appendix 5.9 Scatterplot of the standardised residual and predicted scores for a hierarchical multiple linear regression evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of walking intention



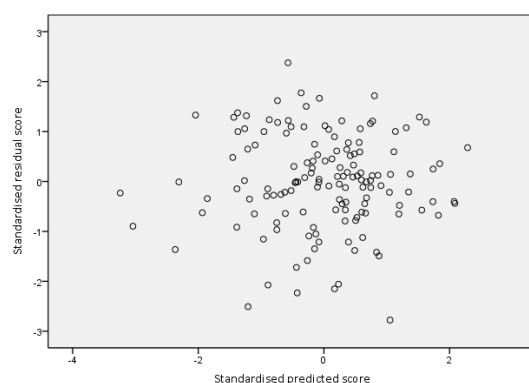
Appendix 5.10 Histogram of the frequencies of standardised residual scores for a hierarchical multiple linear regression evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of 6MWD



Appendix 5.11 Normal P-P plot of standardised residual scores for a hierarchical multiple linear regression evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of 6MWD



Appendix 5.12 Scatterplot of the standardised residual and predicted scores for a hierarchical multiple linear regression evaluating past walking behaviour, walking treatment cognitions, and illness cognitions as determinants of 6MWD



Appendix 6

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Appendix 6.1 Treatment script used in a feasibility study of an RCT of a physiotherapist-led behaviour-change intervention targeting walking for IC^a

Session 1

Open with 3- 5 min general chat. Therapist introduces self, provides overview of session, small talk, getting to know one another, building trust and rapport.

Can you tell me about your health, your leg pain?

- How has it been affecting you?
- What are your biggest problems/worries related to your health?
- How could things in your life be different if you got to grips with these problems/worries?
- What sort of things have you tried to address this so far? How has that gone for you?

[aim is for therapist to identify/elicit value-based goals, barriers to achieving goals]

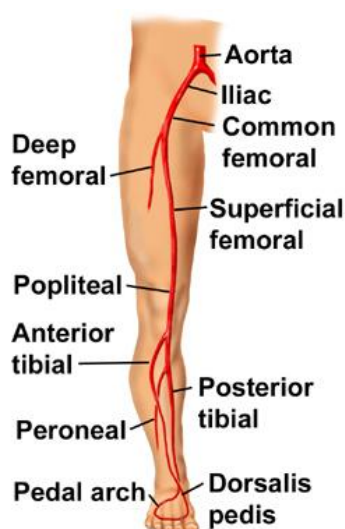
Illness coherence and common sense model

You mentioned [something about how the leg pain affects person] about your leg pain.

- What sort of things have you tried or done to manage this problem?
- How has this gone for you?
- What do you think is going on when you walk?

What is intermittent claudication?

Your arteries carry blood from your lungs around your body to all your different muscles. The blood provides oxygen to the muscles to help them work properly. If your muscles do not get enough oxygen, then they start to hurt. The pain that you feel in your legs when you walk is because your leg muscles are not getting enough oxygen. This is because you have a narrowing in one or more of the arteries supplying your leg, which slows down the flow of blood to that part of your leg.



^aAdapted from Cunningham (2010)

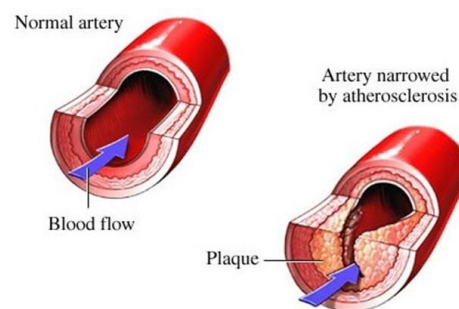
This pain is not a sign of damage to the muscles, but can make walking more difficult, and can affect your ability your work, hobbies and ability to do the everyday things you normally enjoy doing.

- Would you like to talk about the impact your leg pain has had for you?

What causes intermittent claudication?

- Do you have any thoughts on what causes your leg pain?

Narrowing of the arteries is usually the result of the build-up over many years of fatty plaques on the walls of the arteries, called atherosclerosis. When it happens in the legs it can cause leg pain, called intermittent claudication.



- Do you have any thoughts on what might have caused you to develop the narrowing arteries causing your leg pain?

Risk factors you can change

There is no single factor which causes narrowing of the arteries, but I would like to assure you that there are some things which you can do to reduce the risk of continued narrowing or blockage:

- Quitting tobacco smoking
- Managing blood sugar or diabetes
- Reduced cholesterol
- Reduced blood pressure
- Weight loss
- Regular walking exercise

[Therapist reviews risk factors relevant to the individual and current management]

Walking as treatment for IC

Have you had any treatments for your leg pain that you would like to discuss?

Have you heard very much about walking as a treatment to improve your IC?

- Can you tell me about any walking you do now?

- What it is like when you go for a walk?

The benefits of walking for IC

Time and again walking has been shown to have a drastic improvement in the symptoms people with IC experience. A regimen of walking can

1. increase how far or long you can walk before you notice the pain, and
2. increase how far or long you can walk before you need to stop and rest

Regular walking can help you to continue to enjoy work and home activities we discussed earlier. Walking might even be better, in the long term, at improving your symptoms compared with other treatments like angioplasty or bypass, and comes with fewer risks. If you have had an angioplasty or bypass, or undergo this treatment in the future, walking could help with your long-term recovery and maintaining your health and mobility.

What are your thoughts about that?

[Clinician addresses any doubts, concerns or questions as they arise]

How does walking help?

There are at least two ways that walking regularly could improve your symptoms. First, walking leads to changes in the muscles ability to take oxygen from the blood. Second, walking could encourage the blood to find other routes to the muscles and lead to 'collateral blood flow'. In addition, regular walking can support your general health, and protect you from a heart attack or stroke.

In order for walking to help your leg pain, it needs to be done regularly, and progressively, otherwise the benefits will be lost. Engaging in regular activity can be a challenge for most people, and especially for people with leg pain.

[therapist reviews the current walking that patient described earlier]

Based on what we know about walking, it is recommended that people with IC try and walk for a total of **30 minutes**, on **at least 3 days** of the week. It is important that you **“walk through the pain”**. What I mean by this is that, during a walk, if you notice the pain, you should try and continue to walk through the pain until it reaches a **“moderate” intensity**, and then stop and rest for a few minutes before you continue on. [therapist presents 5-point rating of claudication pain to illustrate what is meant by moderate pain]. Some people may notice that their pain does not become moderate, and they can carry on walking without a need to rest. You should try and walk at a **brisk pace that brings on pain within the first 3-5 minutes** of walking.

- Do you have any thoughts or questions so far?
- What are you thinking about your current walking at this point?
- How would you like to be in 4 months' time?

- What would be the benefits of doing more walking?
- What might be the challenges for you to do more walking?
 - In your neighbourhood, for yourself, regarding the walking guidelines?

Rate on a scale from 0 to 10 (with 10 being the highest) how interested you are in making a change to your walking.

- (Why did you not choose a higher number)

Rate, again on a scale from 0 to 10, how confident you are that you can make the change.

- (What would it take to get you to a higher number)
- Is there anybody who could offer you support in making this change?

We talked about very specific guidelines for walking, and for some people it is realistic to begin by doing less and progress slowly until the recommended walking is achieved. But I would like you to think about our talk today, and during our next session we can decide the best way forward for you.

Appendix 6.2 Attention-control script delivered in a feasibility study of an RCT evaluating a physiotherapist-led behaviour-change intervention targeting walking for IC

The attention-control script is consistent with the treatment script up to the section titled, “Risk factors you can change”:

Risk factors you can change

There is no single factor which causes narrowing of the arteries, but I would like to assure you that there are some things which you can do to reduce the risk of continued narrowing or blockage:

- Quitting tobacco smoking
- Managing blood sugar or diabetes
- Reduced cholesterol
- Reduced blood pressure
- Weight loss

[Therapist reviews risk factors relevant to the individual and current management]

How does diet help?

A healthy diet does not require cutting out certain foods and following specific menus. In fact, healthy eating isn't about cutting out foods – it's about eating a wide variety of foods in the right amounts to give your body what it needs.

Healthy eating helps you to maintain a healthy weight and reduces your risk of diabetes, high blood pressure and high cholesterol. It can also help reduce your risk of coronary heart disease and some cancers. If you already have arterial disease, eating well can help protect you from further problems.

Healthy eating has many other benefits too. You may find that you sleep better, have more energy and better concentration – which all adds up.

In order for your diet to make a difference you need to be consistent. You don't need to always get the balance right at every meal, but try to get it right over a longer time, like a whole day or a week.

Based on what we know about diet, it is recommended that people with IC try and reduce their intake of foods high in saturated fats and cholesterol, and incorporate a variety of fresh fruit, vegetables and lean protein sources.

[Therapist reviews specific information provided by the British Heart Foundation]

- Do you have any thoughts or questions so far?
- What are you thinking about your current diet at this point?
- How would you like to be in 4 months' time?
- What would be the benefits of changing your diet?

- What might be the challenges for you to change your diet?

Rate on a scale from 0 to 10 (with 10 being the highest) how interested you are in making a change to your diet.

- (Why did you not choose a higher number)

Rate, again on a scale from 0 to 10, how confident you are that you can make the change.

- (What would it take to get you to a higher number)
- Is there anybody who could offer you support in making this change?

We talked about very specific dietary guidelines, and for some people it is realistic to begin by making small changes. I would like you to think about our talk today, and during our next session we can decide the best way forward for you.

Appendix 6.3 Goal setting and problem solving worksheet used during Session 2 in the treatment and attention-control groups of a feasibility study of an RCT evaluating a physiotherapist-led behaviour-change intervention targeting walking for IC^a

During last week's session, we talked about intermittent claudication, which is the word used to describe your leg pain. We talked about how blood is carried to your legs through your arteries, and how the arteries can become blocked, and cause this pain.

Did you have any questions about that?

We also discussed some of the factors that put you at risk of this problem, and things that you can do to improve your health, like walking for exercise. We covered some of the benefits of walking and a where you would like to be with your walking in 4 months.

You mentioned [revisit any points the participant made with regard to a) where they would like to be; b) how interested they are in walking more; c) who might be able to support them etc.]

This week, I would like to help you build a plan to make the changes that we discussed.

The changes I want to make are:

The most important reasons why I want to make these changes are:

My specific goal is:

To achieve this goal:

What am I going to do?

Where am I going to do it?

When am I going to do it?

WITH whom am I going to do it?

Up to 3 possible barriers that might hinder me from sticking to my plan are:

1)

2)

3)

How am I going to overcome these barriers?

1)

2)

3)

I will know my plan is working if:

[Participants are given a laminated copy of their action plan to take home where they can record their activity]

Appendix 6.4 Telephone booster session worksheet for the treatment and attention control groups of a feasibility study of an RCT evaluating a physiotherapist-led behaviour-change intervention targeting walking among individuals with IC^a

When we met, we discussed your goal to [patients specific goal] and we agreed on a plan for how you could achieve this goal.

How is it going with your plan?

- Identify attempts and successes and reinforce these efforts
- Reinforce values underlying goals and check these are still salient
- Discuss any aspects of the plan that have been difficult to achieve
- Revise goals and plans if necessary
- Revisit strategies for addressing barriers
- Discuss new barrier and strategies to overcome these

Is there anything else you would like to discuss?

Is there any other way that I can help you today?

[Remind participant of next booster call]

^aAdapted from Cunningham (2010)

Appendix 6.5 Acceptability of the plan and script of a behaviour-change intervention targeting walking among individuals with IC

Participant	Intervention structure
110B	Some individuals might prefer to go to a centre, but home visits could be more helpful because the physiotherapist can see the context where the person is walking and give advice.
113B	Would prefer to go to a centre, did not specify a reason why.
115B	Likes the idea and would prefer someone to come to her home and likes the idea.
116B	Would be embarrassed to have someone at his home because it is untidy.
117B	Has no need for physiotherapy, he can do it himself: "What more could I know about walking?"
123B	Having a physiotherapist visit the home is a fantastic idea, it saves a lot of hassle, especially for people who have a lot of trouble walking or leaving the house. However, it might be less relevant or appropriate for her because she has other pain problems, like back pain, that limit her, and not just claudication.
	Intervention script
110B	Was confused or interested by the text: "You may worry that walking will harm your legs because of the cramping pain you experience when you walk. There is no evidence that this is the case. In fact, lots of research has shown that walking more will help improve how far you can walk before the pain comes on." Patient wonders what causes it then, if pain is not causing the problem. Unsure of the meaning of "metabolism".
113B	Unsure of the meaning of the word "atherosclerosis". Already aware of information on risk factors, and blocked arteries.
115B	She is surprised to see the risk factors do not include "diet", although obesity is shown.
116B	Already aware of information about IC, provided by vascular specialist. This would have been more helpful at an earlier stage. Unsure of the meaning and pronunciation of "atherosclerosis", although acknowledges that the script explains this later on. Wonders where obesity fits into it, and how you define or determine if you are obese.
117B	The material is really helpful and informative, and novel. Does not understand the word "atherosclerosis", otherwise the text is very clear and positive to read.
123B	Already aware risk factors presented, but it would be great for someone who is newly diagnosed. The list of risk factors are important to discuss with the physiotherapist, she would want as much information as possible on what she should/should not do with relevance to risk factors she has. She would want to know what sort of exercises help, and to be shown exactly what to do as far as she is able to exercise.
124B	Already knew most of this, but it is nice to have it confirmed. Would want to know the best kind of exercise to do, and the regularity of it. And if there are any drugs he could take to alleviate the pain.
127B	Not particularly useful for him, as he is already aware of his problems and risk factors, and already does a lot of walking. But for others, it might be useful.
	Intervention diagram
110B	Helps to see what is happening inside of the body. He had never really imagined this before. Prompted the patient wonder just how exercise would clear the blockage. He wanted more information on how the two were linked.

- 113B Needs interpreting, diagram is a little bit complex for the ordinary person. Would like to know which arteries in *my* legs are actually blocked. The diagram of a blocked artery is familiar, but it is helpful to see it.
- 115B A bit “frightening” to look at! But at least you learn something. Patient relates image to her own bypass and is able to locate the place where she has had a bypass.
- 116B Useful and can make sense of them, especially the furring of the artery as he has high cholesterol.
- 117B Helpful to see, maybe move some of the text to the left side to spread it out. Diagram of the blocked artery is not useful at all on its own: there needs to be explanatory text around it and perhaps also a cross-sectional diagram showing the space remaining where the blood can flow through.
- 123B Very interesting, wanted to see where she gets her pain, and can see how collateral vessels would develop here. The blocked artery is quite frightening, clear message of what is happening in the body. It is clear to see the narrowing and how little blood could pass through – helps to understand why you have the pain.
- 124B Provides much more detail of the problem, and helps to make sense of the pain and what causes it. Patient can relate to this, and it is just how he imagined it.
- 127B Shows where the blood circulates, but the writing is too small, able to understand the image, quite a lot of writing. Blocked artery: looks like a pipe-line, should be “uglier”, maybe larger and in colour to have more of an impact on the patient.

Participants were n=6 male, mean age 60 years (range 56–78), mean 6 Minute Walk Distance 338.40 metres (range 237.11–466.20).

Appendix 6.6 Self-report assessment of sociodemographic and clinical characteristics of participants with IC in a feasibility study of an RCT evaluating a physiotherapist-led behaviour-change intervention targeting walking

Please complete all questions to the best of your ability.

Age: _____

Gender: ☐ Male ☐ Female

What is your marital or same-sex civil partnership status?

- ☐ Never married
- ☐ Married
- ☐ Separated, but still legally married
- ☐ Divorced
- ☐ Widowed

Which of the following best describes your ethnic group or background?

- ☐ White
- ☐ Asian/Asian British
- ☐ Black/African/Caribbean/Black British
- ☐ Mixed/multiple ethnic background
- ☐ Other ethnic group (please specify: _____)

Smoking history (check the box that best applies to you):

- ☐ I am currently a cigarette smoker
- ☐ I have quit or cut down on smoking within the past 6 months
- ☐ I used to smoke, but have not smoked a cigarette for at least 6 months
- ☐ I have never been a cigarette smoker

Are you, or have you ever been, diagnosed with:

Diabetes mellitus	Yes <input type="checkbox"/> No <input type="checkbox"/>
Cholesterol	Yes <input type="checkbox"/> No <input type="checkbox"/>
High blood pressure	Yes <input type="checkbox"/> No <input type="checkbox"/>
Cardiovascular disease	Yes <input type="checkbox"/> No <input type="checkbox"/>
Kidney disease	Yes <input type="checkbox"/> No <input type="checkbox"/>

Have you ever experienced a:

Heart attack	Yes <input type="checkbox"/> No <input type="checkbox"/>
Stroke	Yes <input type="checkbox"/> No <input type="checkbox"/>

Are you on any medication which helps to treat or alleviate the **pain** or **discomfort** that you experience in your legs during walking?

Yes ☐ No ☐

For how long have you had pain or discomfort in your legs when walking that is due to poor circulation?

- ☐ <1 year
- ☐ 1 – 2 years
- ☐ >2 years

Do you have pain or discomfort caused by a condition other than the circulation in your legs (e.g. foot or back pain, arthritis, knee injury, etc.) that affects your ability to walk?

Yes ☐ No ☐

If you answered, “Yes”, write down what this condition is here: _____

Have you received medical advice on how far or how long to walk because of your intermittent claudication?

Yes ☐ No ☐

In the past 3 years, have you taken part in an exercise programme at a centre in your community or at your hospital?

Yes ☐ No ☐

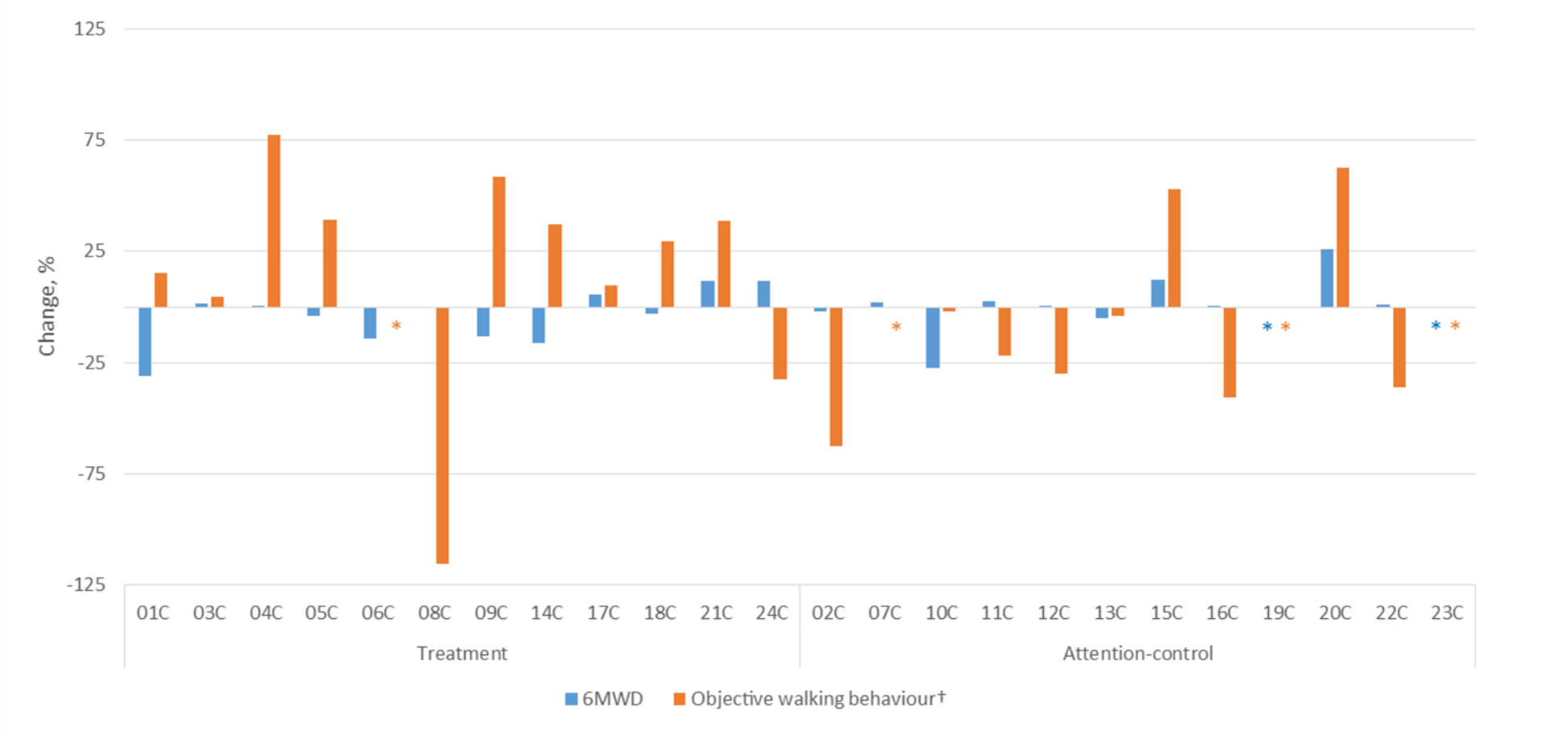
Appendix 6.7 Patterns of missing data across participants in the treatment and attention-control groups in a feasibility study of an RCT of a behaviour-change intervention targeting walking among individuals with IC

Variable	MDR, %	Treatment												Attention-control											
		1	3	4	5	6	8	9	14	17	18	21	24	2	7	10	11	12	13	15	26	19	20	22	23
Baseline																									
Attitude	4.5																	•							
Subjective norm	4.5																	•							
PBC	9.0																•	•							
Intention	4.5																	•							
Identity	0																								
Coherence	0																								
Personal control	0																								
Treatment control	0																								
Timeline acute	0																								
Timeline cyclical	0																								
Consequences	0																								
Emotion	0																								
Risk factors ^a	0																								
Personality ^a	0																								
Accident/chance ^a	4.5																	•							
Immunity ^a	0																								
Barrier self-efficacy	0																								
SF-12v2 MCS	0																								
SF-12v2 PCS	0																								
BASIC	0																								
6MWD	0																								
6-Day Step Count	36.4			•		•	•						•		•			•	•			•	•		
Post-Intervention																									
Attitude	22.7							•	•	•									•			•	•		
Subjective norm	31.8						•	•	•	•					•				•			•	•		
PBC	22.7							•	•	•									•			•	•		
Intention	22.7							•	•	•									•			•	•		
Identity	18.2								•	•									•			•	•		
Coherence	22.7								•	•			•						•			•	•		
Personal control	22.7								•	•			•						•			•	•		
Treatment control	22.7								•	•			•						•			•	•		
Timeline acute	27.3								•	•		•	•						•			•	•		

Timeline cyclical	22.7		•	•	•		•	•	•	
Consequences	22.7		•	•	•		•	•	•	
Emotion	22.7		•	•	•		•	•	•	•
Risk factors ^a	31.8		•	•	•	•	•	•	•	
Personality ^a	18.2		•	•			•	•	•	
Accident/chance ^a	18.2		•	•			•	•	•	
Immunity ^a	18.2		•	•			•	•	•	
Barrier self-efficacy	22.7	•	•	•			•	•	•	
Action planning	18.2		•	•			•	•	•	
Action control	22.7	•	•	•	•		•	•	•	
Follow-up										
Attitude	0							•		•
Subjective norm	0							•		•
PBC	0							•		•
Intention	0							•		•
Identity	0							•		•
Coherence	0							•		•
Personal control	0							•		•
Treatment control	0							•		•
Timeline acute	0							•		•
Timeline cyclical	0							•		•
Consequences	0							•		•
Emotion	0							•		•
Risk factors ^a	0							•		•
Personality ^a	0							•		•
Accident/chance ^a	0							•		•
Immunity ^a	0							•		•
Barrier self-efficacy	0							•		•
SF-12v2 MCS	4.5							•	•	•
SF-12v2 PCS	4.5							•	•	•
BASIC	0							•		•
6MWD	0							•		•
6-Day Step Count	9.1	•					•	•		•

^aCausal attributions. BASIC, Baltimore Activity Scale for Intermittent Claudication; CA, Causal attribution; MDR, missing data rate (excluding participants 19 and 23 who were lost to follow-up; n=22); PBC, perceived behavioural control; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-12v2, Medical Outcomes Survey Short Form-12 version 2; 6MWD, 6 minute walk distance.

Appendix 6.8 Change in 6MWD and objective walking behaviour among participants with IC in a feasibility study of an RCT of a behaviour-change intervention targeting walking



*Missing data. †Mean of 3 day pedometer data. Participant 08C underwent an abdominal operation, and reported this as a barrier to achieving her planned walking.

Appendix 6.9 Box plot illustrating median (IQR) change scores for 6MWD and three outliers for data reflecting 6MWD in the attention-control group of a feasibility study of an RCT evaluating a physiotherapist-led behaviour-change intervention targeting walking for IC

